PART III: CONSUMER INFORMATION

PrHUMIRA®

40 mg/0.8 mL subcutaneous injection (Pre-filled syringe/Pen)
adalimumab

This leaflet is PART III of a three-part Product Monograph published when HUMIRA (Hu-MEER-ah) was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about HUMIRA. Contact the doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

HUMIRA treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the HUMIRA efficacy and safety profile.

What the medication is used for:

HUMIRA is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed HUMIRA to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given HUMIRA. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given HUMIRA to reduce the signs and symptoms of your/your child's disease.

What it does:

HUMIRA is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HUMIRA binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, HUMIRA decreases the inflammation process of these diseases.

HUMIRA helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, HUMIRA helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). HUMIRA may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). HUMIRA may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

HUMIRA is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

HUMIRA also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

HUMIRA helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

HUMIRA, however, can also lower your/your child's body's ability to fight infections. Taking HUMIRA can make you/your child more prone to getting infections or make any infection you/your child have worse.

When it should not be used:

You/your child should not take HUMIRA if you/your child have:

- an allergy to any of the ingredients in HUMIRA (see **What the important non-medicinal ingredients are** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

What the medicinal ingredient is:

adalimumab

What the important non-medicinal ingredients are:

citric acid monohydrate, dibasic sodium phosphate dihydrate, mannitol, monobasic sodium phosphate dihydrate, polysorbate 80, sodium citrate, sodium chloride

For a full listing of non-medicinal ingredients, see PART I of the Product Monograph.

What dosage forms it comes in:

HUMIRA is available in the following forms:

- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)

All packaging components are latex-free.

HUMIRA is also available in the following forms:

- Single-use, 1 mL pre-filled glass syringe containing 10 mg adalimumab dissolved in 0.1 mL sterile solution (100 mg/mL) for pediatric use only
- Single-use, 1 mL pre-filled glass syringe containing 20 mg adalimumab dissolved in 0.2 mL sterile solution (100 mg/mL) for pediatric use only
- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled Pen containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)
- Single-use, 1 mL vial containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) for pediatric use

WARNINGS AND PRECAUTIONS

Before starting, during and after treatment with HUMIRA, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your/your child's immune system, HUMIRA can cause serious side effects. The possible serious side effects include:

Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking HUMIRA, call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with HUMIRA. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and HUMIRA is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking HUMIRA or other TNF-blockers. Some patients receiving HUMIRA have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take HUMIRA or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including HUMIRA, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.

- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.

- **Serious infections:** There have been rare cases where patients taking HUMIRA or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.

- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

If you/your child received HUMIRA while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of HUMIRA received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her HUMIRA use during pregnancy so they can decide when your/her baby should receive any vaccine.

BEFORE you/your child use HUMIRA, talk to the doctor or pharmacist if:

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from HUMIRA. If you are unsure, ask your/your child's doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take HUMIRA, these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with HUMIRA.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting HUMIRA.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking HUMIRA. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking HUMIRA.
- you/your child are taking other medicines for your/your child's Crohn's disease or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking HUMIRA. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking HUMIRA.
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

If you are not sure or have any questions about any of this information, ask your/your child's doctor.

INTERACTIONS WITH THIS MEDICATION

You/your child should not take HUMIRA with:

- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orencia®)
- anakinra (Kineret®)

If you have questions, ask your/your child's doctor.

PROPER USE OF THIS MEDICATION

HUMIRA is administered by injection under the skin (by subcutaneous injection).

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of HUMIRA is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of HUMIRA is 40 mg every other week.

For patients who do not require a full 40 mg dose of HUMIRA, a 40 mg vial, a 10 mg pre-filled syringe or a 20 mg pre-filled syringe is also available.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Children, 13 to 17 years of age weighing ≥ 40 kg, with Crohn's disease:

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of HUMIRA, a 40 mg vial or a 20 mg pre-filled syringe is also available.

Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of HUMIRA is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of HUMIRA is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of HUMIRA, a 40 mg vial is also available.

Overdose:

If you/your child accidentally inject HUMIRA more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

Missed Dose:

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of HUMIRA as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

Administration:

The following instructions explain how to inject HUMIRA. Please read the instructions carefully and follow them step-by-step. You will be instructed by your/your child's doctor or assistant on the technique of injection. Do not attempt to inject

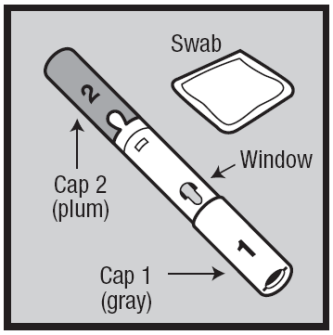
until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person; for example, a healthcare professional, a family member or friend. The AbbVie Care patient assistance program is also available to you/your child if you/your child require assistance with injections should you prefer nurse-administered injections for you/your child.

This injection should not be mixed in the same syringe with any other medicine.

Step 1. Setting Up

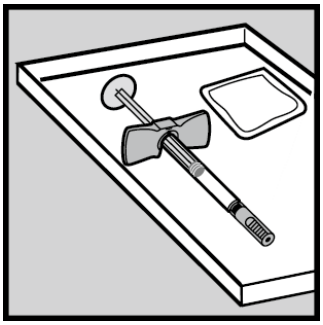
- You will need one alcohol pad/swab and a cotton ball or gauze pad (not included in the HUMIRA carton).
- Remove one dose tray containing a HUMIRA Pen or pre-filled syringe from the box in the refrigerator.
  - Do not shake or drop the Pen or pre-filled syringe.
  - Do not use the Pen or pre-filled syringe if it is frozen or if it has been left in direct sunlight.
  - If you are using the Pen, only remove the caps **immediately** before injection.
- Set up the following on a clean, flat working surface:

  - One HUMIRA Pen
  - One alcohol pad (swab)



-OR-

  - One pre-filled syringe of HUMIRA for injection
  - One alcohol pad (swab)

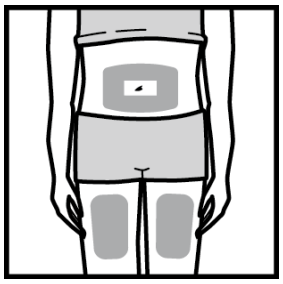


- If you do not have all of the pieces you need to give yourself/your child an injection, call your pharmacist. Use only the items provided in the box your HUMIRA prescription comes in (except for the alcohol pad/swab and cotton ball or gauze pad, which are not included in the HUMIRA carton).
- Make sure that the name HUMIRA appears on the dose tray and Pen or pre-filled syringe label.
- Check the expiry date on the Pen or pre-filled syringe. Do not use the product if the date has passed the month and year shown.
- Make sure the liquid in the Pen or pre-filled syringe is clear and colourless. Do not use the Pen or pre-filled syringe if the liquid is cloudy or discoloured or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing of the used Pen, needles and syringe.

FOR YOUR/YOUR CHILD'S PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.

Step 2. Choosing and Preparing the Injection Site

- Wash your hands thoroughly.
- Choose a site on the front of your/your child's thighs or abdomen. If you choose your/your child's abdomen, you should avoid the area two inches around your/your child's navel.
- Choose a different site each time you give yourself/your child an injection. Each new injection should be given at least one inch from a site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you/your child have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.

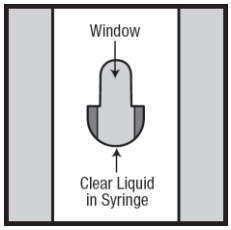


- Wipe the injection site where HUMIRA is to be injected with an alcohol pad (swab), using a circular motion. Do **NOT** touch this area again before giving the injection.

Step 3. Preparing the Dose for Injection

<u>HUMIRA Pen</u>

- Hold the Pen with the gray cap pointing up. Check the appearance of the solution through the window on the side of the Pen to make sure the liquid is clear and colourless. Do not use the Pen if the liquid is cloudy or discoloured or has flakes or particles in it. Do not use if frozen or if it has been left in direct sunlight.



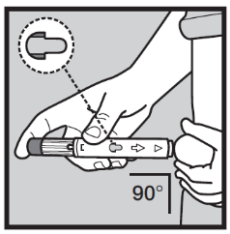
HUMIRA Pre-Filled Syringe

- Remove the needle cover from the syringe, taking care not to touch the needle with your fingers or allowing it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle, this is acceptable.

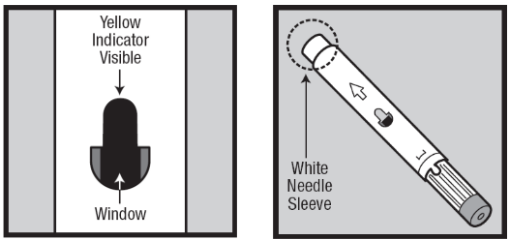
Step 4. Injecting HUMIRA

HUMIRA Pen

- Only remove the caps **immediately** before injection.
- Hold the gray body of the Pen with one hand.
  - Place your hand on the middle of the Pen so that neither the gray cap (Cap 1) nor the plum cap (Cap 2) is covered.
  - Hold the Pen with the gray cap (Cap 1) pointing up.
- With your other hand, pull the gray cap (Cap 1) straight off (without twisting) and discard the cap.
  - Check that the small needle cover of the syringe has been removed with the cap.
  - If a few small drops of liquid come out of the needle, this is acceptable.
  - The white needle sleeve, which covers the needle, will now be exposed. Do not try to touch the needle housed in the barrel.
  - **DO NOT RECAP as you may damage the needle**.
  - Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Pull the plum safety cap (Cap 2) straight off (without twisting) to expose the plum-coloured activation button. The Pen is now ready to use.
  - Please note that the Pen is activated after removing Cap 2 and that pressing the button under Cap 2 will immediately result in discharge of medication.
  - Do not press the plum-coloured activation button until properly positioned.
  - **DO NOT RECAP as this could cause the unit to discharge**.
- Hold the Pen so that the window is in view. The presence of one or more bubbles in the window is normal.
- With your free hand, gently squeeze a sizable area of the cleaned skin at the injection site and hold firmly. You will inject into this raised area of skin.
- Place the white end of the Pen straight (a 90° angle) and flat against the raised area of skin with the arrow on the Pen pointing toward the injection site. Position the Pen so that it will not inject the needle into your fingers.
- With your index finger or thumb, press the plum-coloured button to begin the injection.
  - Try not to cover the window.
  - Note that you will hear a loud ‘click’ when you press the button, which indicates the start of the injection. You/your child will feel a small prick as the needle advances.
  - Keep pressing and continue to hold the Pen with steady pressure in place for about **10 seconds to ensure complete injection**. A way to remember is simply ‘click and count to 10’. Do not remove the Pen while the injection is being given.
  - It is important to maintain steady pressure at the injection site for the entire period of time.



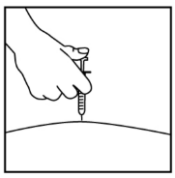
- You will see a yellow indicator move into the window during the injection. The injection is complete when the yellow indicator stops moving.
- Lift the Pen straight up from the injection site. The white needle sleeve will move down over the needle and lock into place over the needle tip. Do not try to touch the needle. The white needle sleeve is there to protect you/your child from touching the needle.



- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you/your child have slight bleeding, this is normal.
- Dispose of the Pen immediately into your special sharps container.

HUMIRA Pre-Filled Syringe

- With one hand, gently pinch the cleaned area of skin and hold it firmly. With the other hand, hold the syringe like a pencil at about a 90° angle to the skin.



- With a quick, short, “dart-like” motion, push the needle into the skin.

- After the needle is in, let go of the skin. If blood appears in the syringe, it means that you have entered a blood vessel. Do not inject HUMIRA. Withdraw the needle and repeat the steps to choose and clean a new injection site. However, do **NOT** use the same syringe (discard the syringe in your puncture-proof container). If no blood appears, slowly push the plunger all the way in until all of the HUMIRA is injected.
- When the syringe is empty, remove the needle from the skin, being careful to keep it at the same angle as it was when it was inserted.
- Immediately press a cotton ball or gauze pad over the injection site and hold for 10 seconds. Slight bleeding may occur. Do **NOT** rub the injection site. A bandage is optional.
- Dispose of the syringe immediately into your special sharps container.

Step 5. Disposing of Supplies

- You should always check with your/your child's healthcare provider (e.g., doctor, nurse, or pharmacist) for instructions on how to properly dispose of used needles and syringes (including the Pen). Do **NOT** use the same needle and syringe more than once. You should follow any special provincial or local laws regarding the proper disposal of needles and syringes. **Do NOT throw used needles or syringes (including the Pen) in the household trash or recycling bin**.
- Dispose of used needles and syringes (including the Pen) in a container made especially for this purpose (sharps container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". Do not use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child's doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- The used alcohol pads may be placed in the trash, unless otherwise instructed by your/your child's doctor, nurse or pharmacist. The dose tray and cover may be recycled.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, HUMIRA can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your/your child's doctor <u>immediately</u> if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets

Tell the doctor <u>as soon as possible</u> if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
		Only if severe	In all cases	
Very Common	Injection site reaction		✓	
Common	Cough and cold symptoms, including sore throat		✓	
	Headache	✓		
	Rash		✓	
	Nausea		✓	
	Pneumonia		✓	✓
	Fever		✓	
	Abdominal pain	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Tuberculosis		✓	✓
	Other serious infections		✓	✓
	Nerve disorder		✓	✓
	Appendicitis		✓	✓
	Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
	Bladder infection (painful urination)		✓	✓
	Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking HUMIRA, contact your/your child's doctor or pharmacist.

HOW TO STORE IT

Keep HUMIRA and all other medicines out of the reach of children.

Store between 2 and 8ºC (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE HUMIRA.** Protect from light. Refrigerated HUMIRA remains stable until the expiration date printed on the Pen or pre-filled syringe. Do not use beyond the expiration date.

When needed, for example when you/your child are travelling, a HUMIRA Pen or pre-filled syringe can be stored at room temperature (up to 25ºC/77ºF) for a single maximum period of 14 days.

Once taken out of the refrigerator for room temperature storage, a HUMIRA Pen or pre-filled syringe must be used within 14 days, even if it is put back in the refrigerator. If not used within 14 days, the HUMIRA Pen or pre-filled syringe must be discarded. You should record the date when the HUMIRA Pen or pre-filled syringe is first removed from the refrigerator.

Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

General Advice About Prescription Medicines

Talk to your/your child's doctor or other healthcare provider if you have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **CONSUMER INFORMATION** leaflet. If you have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you information about this medicine that was written for healthcare professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-866-8HUMIRA (1-866-848-6472).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

NOTE: Should you require information related to the management of side effects, contact your/your child's healthcare professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at 1-866-8HUMIRA (1-866-848-6472).

This leaflet was prepared by AbbVie Corporation.

Last revised: June 25, 2019

PART III: CONSUMER INFORMATION

PrHUMIRA®

10 mg/0.1 mL subcutaneous injection (Pre-filled syringe)*

20 mg/0.2 mL subcutaneous injection (Pre-filled syringe)*

40 mg/0.4 mL subcutaneous injection (Pre-filled syringe/Pen)

80 mg/0.8 mL subcutaneous injection (Pre-filled syringe/Pen)
adalimumab

***For pediatric use only**

This leaflet is PART III of a three-part Product Monograph published when HUMIRA (Hu-MEER-ah) was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about HUMIRA. Contact the doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

HUMIRA treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the HUMIRA efficacy and safety profile.

What the medication is used for:

HUMIRA is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed HUMIRA to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given HUMIRA. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given HUMIRA to reduce the signs and symptoms of your/your child's disease.

What it does:

HUMIRA is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HUMIRA binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, HUMIRA decreases the inflammation process of these diseases.

HUMIRA helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, HUMIRA helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). HUMIRA may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). HUMIRA may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

HUMIRA is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

HUMIRA also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

HUMIRA helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

HUMIRA, however, can also lower your/your child's body's ability to fight infections. Taking HUMIRA can make you/your

child more prone to getting infections or make any infection you/your child have worse.

When it should not be used:

You/your child should not take HUMIRA if you/your child have:

- an allergy to any of the ingredients in HUMIRA (see **What the important non-medicinal ingredients are** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

What the medicinal ingredient is:

adalimumab

What the important non-medicinal ingredients are:

mannitol, polysorbate 80

For a full listing of non-medicinal ingredients, see PART I of the Product Monograph.

What dosage forms it comes in:

HUMIRA is available in the following forms:

- Single-use, 1 mL pre-filled glass syringe containing 10 mg adalimumab dissolved in 0.1 mL sterile solution (100 mg/mL) for pediatric use only
- Single-use, 1 mL pre-filled glass syringe containing 20 mg adalimumab dissolved in 0.2 mL sterile solution (100 mg/mL) for pediatric use only
- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled Pen containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)

All packaging components are latex-free.

HUMIRA is also available in the following forms:

- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL vial containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) for pediatric use

WARNINGS AND PRECAUTIONS

Before starting, during and after treatment with HUMIRA, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your/your child's immune system, HUMIRA can cause serious side effects. The possible serious side effects include:

Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking HUMIRA, call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with HUMIRA. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and HUMIRA is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking HUMIRA or other TNF-blockers. Some patients receiving HUMIRA have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take HUMIRA or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including HUMIRA, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.

- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.

- **Serious infections:** There have been rare cases where patients taking HUMIRA or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.

- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

If you/your child received HUMIRA while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of HUMIRA received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her HUMIRA use during pregnancy so they can decide when your/her baby should receive any vaccine.

BEFORE you/your child use HUMIRA, talk to the doctor or pharmacist if:

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from HUMIRA. If you are unsure, ask your/your child's doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take HUMIRA, these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with HUMIRA.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting HUMIRA.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking HUMIRA. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking HUMIRA.
- you/your child are taking other medicines for your/your child's Crohn's disease or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking HUMIRA. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking HUMIRA.
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

If you are not sure or have any questions about any of this information, ask your/your child's doctor.

INTERACTIONS WITH THIS MEDICATION

You/your child should not take HUMIRA with:

- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orencia®)
- anakinra (Kineret®)

If you have questions, ask your/your child's doctor.

PROPER USE OF THIS MEDICATION

HUMIRA is administered by injection under the skin (by subcutaneous injection).

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of HUMIRA is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of HUMIRA is 40 mg every other week.

For patients who do not require a full 40 mg dose of HUMIRA, a 40 mg vial, a 10 mg pre-filled syringe or a 20 mg pre-filled syringe is also available.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40 mg injections or two 80 mg injections) or split over two consecutive days (two 40 mg injections or one 80 mg injection each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections or one 80 mg injection in one day.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections or two 80 mg injections) or split over two consecutive days (two 40 mg injections or one 80 mg injection each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections or one 80 mg injection in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose administered by subcutaneous injection. The first dose of 80 mg can be given as two 40 mg injections or one 80 mg injection.

Children, 13 to 17 years of age weighing ≥ 40 kg, with Crohn's disease:

- The recommended dose is 160 mg initially at Week 0 followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40 mg injections or two 80 mg injections), or split over two consecutive days (two 40 mg injections or one 80 mg injection each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections or one 80 mg injection in one day. At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of HUMIRA, a 40 mg vial or a 20 mg pre-filled syringe is also available.

Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection (two 40 mg injections or one 80 mg injection), followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of HUMIRA is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of HUMIRA is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of HUMIRA, a 40 mg vial is also available.

Overdose:

If you/your child accidentally inject HUMIRA more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

Missed Dose:

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of HUMIRA as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

Administration:

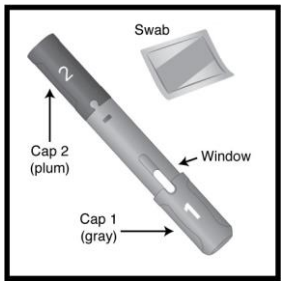
The following instructions explain how to inject HUMIRA. Please read the instructions carefully and follow them step-by-step. You will be instructed by your/your child's doctor or assistant on the technique of injection. Do not attempt to inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person; for example, a healthcare professional, a family member or friend. The AbbVie Care patient assistance program is also available to you/your child if you/your child require assistance with injections should you prefer nurse-administered injections for you/your child.

This injection should not be mixed in the same syringe with any other medicine.

Step 1. Setting Up

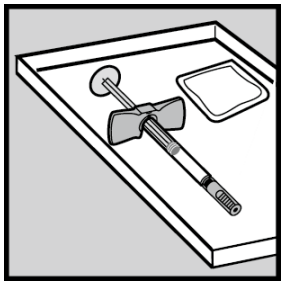
- You will need one alcohol pad/swab and a cotton ball or gauze pad (not included in the HUMIRA carton).
- Remove one dose tray containing a HUMIRA Pen or pre-filled syringe from the box in the refrigerator.
  - Do not shake or drop the Pen or pre-filled syringe.
  - Do not use the Pen or pre-filled syringe if it is frozen or if it has been left in direct sunlight.
  - If you are using the Pen, only remove the caps **immediately** before injection.
- Set up the following on a clean, flat working surface:

  - One HUMIRA Pen
  - One alcohol pad (swab)



-OR-

  - One pre-filled syringe of HUMIRA for injection
  - One alcohol pad (swab)

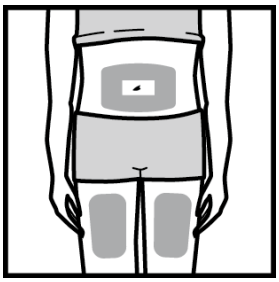


- If you do not have all of the pieces you need to give yourself/your child an injection, call your pharmacist. Use only the items provided in the box your HUMIRA prescription comes in (except for the alcohol pad/swab and cotton ball or gauze pad, which are not included in the HUMIRA carton).
- Make sure that the name HUMIRA appears on the dose tray and Pen or pre-filled syringe label.
- Check the expiry date on the Pen or pre-filled syringe. Do not use the product if the date has passed the month and year shown.
- Make sure the liquid in the Pen or pre-filled syringe is clear and colourless. Do not use the Pen or pre-filled syringe if the liquid is cloudy or discoloured or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing of the used Pen, needles and syringe.

FOR YOUR/YOUR CHILD'S PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.

Step 2. Choosing and Preparing the Injection Site

- Wash your hands thoroughly.
- Choose a site on the front of your/your child's thighs or abdomen. If you choose your/your child's abdomen, you should avoid the area two inches around your/your child's navel.
- Choose a different site each time you give yourself/your child an injection. Each new injection should be given at least one inch from a site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you/your child have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.

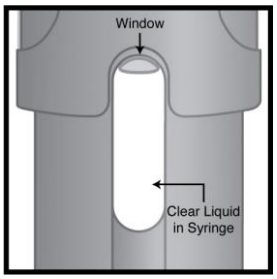


- Wipe the injection site where HUMIRA is to be injected with an alcohol pad (swab), using a circular motion. Do **NOT** touch this area again before giving the injection.

Step 3. Preparing the Dose for Injection

HUMIRA Pen

- Hold the Pen with the gray cap pointing up. Check the appearance of the solution through the window on the side of the Pen to make sure the liquid is clear and colourless. Do not use the Pen if the liquid is cloudy or discoloured or has flakes or particles in it. Do not use if frozen or if it has been left in direct sunlight.



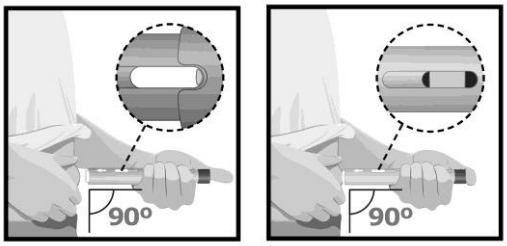
HUMIRA Pre-Filled Syringe

- Remove the needle cover from the syringe, taking care not to touch the needle with your fingers or allowing it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle, this is acceptable.

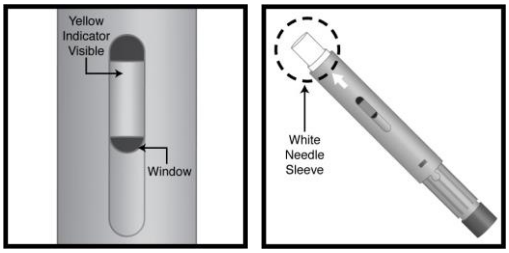
Step 4. Injecting HUMIRA

HUMIRA Pen

- Only remove the caps **immediately** before injection.
- Hold the gray body of the Pen with one hand.
  - Place your hand on the middle of the Pen so that neither the gray cap (Cap 1) nor the plum cap (Cap 2) is covered.
  - Hold the Pen with the gray cap (Cap 1) pointing up.
- With your other hand, pull the gray cap (Cap 1) straight off (without twisting) and discard the cap.
  - Check that the small needle cover of the syringe has been removed with the cap.
  - If a few small drops of liquid come out of the needle, this is acceptable.
  - The white needle sleeve, which covers the needle, will now be exposed. Do not try to touch the needle housed in the barrel.
  - **DO NOT RECAP as you may damage the needle**.
  - Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Pull the plum safety cap (Cap 2) straight off (without twisting) to expose the plum-coloured activation button. The Pen is now ready to use.
  - Please note that the Pen is activated after removing Cap 2 and that pressing the button under Cap 2 will immediately result in discharge of medication.
  - Do not press the plum-coloured activation button until properly positioned.
  - **DO NOT RECAP as this could cause the unit to discharge**.
- Hold the Pen so that the window is in view. The presence of one or more bubbles in the window is normal.
- With your free hand, gently squeeze a sizable area of the cleaned skin at the injection site and hold firmly. You will inject into this raised area of skin.
- Place the white end of the Pen straight (a 90° angle) and flat against the raised area of skin with the white arrow on the Pen pointing toward the injection site. Position the Pen so that it will not inject the needle into your fingers.
- With your index finger or thumb, press the plum-coloured button to begin the injection.
  - Try not to cover the window.
  - Note that you will hear a loud ‘click’ when you press the button, which indicates the start of the injection. You/your child will feel a small prick as the needle advances.
  - Keep pressing and continue to hold the Pen with steady pressure in place for about **10 seconds to ensure complete injection**. A way to remember is simply ‘click and count to 10’. Do not remove the Pen while the injection is being given.
  - It is important to maintain steady pressure at the injection site for the entire period of time.



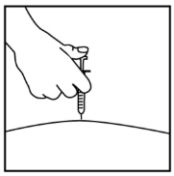
- You will see a yellow indicator move into the window during the injection. The injection is complete when the yellow indicator stops moving.
- Lift the Pen straight up from the injection site. The white needle sleeve will move down over the needle and lock into place over the needle tip. Do not try to touch the needle. The white needle sleeve is there to protect you/your child from touching the needle.



- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you/your child have slight bleeding, this is normal.
- Dispose of the Pen immediately into your special sharps container.

HUMIRA Pre-Filled Syringe

- With one hand, gently pinch the cleaned area of skin and hold it firmly. With the other hand, hold the syringe like a pencil at about a 90° angle to the skin.



- With a quick, short, "dart-like" motion, push the needle into the skin.
- After the needle is in, let go of the skin. If blood appears in the syringe, it means that you have entered a blood vessel. Do not inject HUMIRA. Withdraw the needle and repeat the steps to choose and clean a new injection site. However, do **NOT** use the same syringe (discard the syringe in your puncture-proof container). If no blood appears, slowly push the plunger all the way in until all of the HUMIRA is injected.
- When the syringe is empty, remove the needle from the skin, being careful to keep it at the same angle as it was when it was inserted.
- Immediately press a cotton ball or gauze pad over the injection site and hold for 10 seconds. Slight bleeding may occur. Do **NOT** rub the injection site. A bandage is optional.
- Dispose of the syringe immediately into your special sharps container.

Step 5. Disposing of Supplies

- You should always check with your/your child's healthcare provider (e.g., doctor, nurse, or pharmacist) for instructions on how to properly dispose of used needles and syringes (including the Pen). Do **NOT** use the same needle and syringe more than once. You should follow any special provincial or local laws regarding the proper disposal of needles and syringes. **Do NOT throw used needles or syringes (including the Pen) in the household trash or recycling bin**.
- Dispose of used needles and syringes (including the Pen) in a container made especially for this purpose (sharps container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". Do not use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child's doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- The used alcohol pads may be placed in the trash, unless otherwise instructed by your/your child's doctor, nurse or pharmacist. The dose tray and cover may be recycled.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, HUMIRA can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

You may feel less injection site pain when using HUMIRA 40 mg/0.4 mL compared to HUMIRA 40 mg/0.8 mL.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets

Tell the doctor as soon as possible if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
		Only if severe	In all cases	
Very Common	Injection site reaction		✓	
Common	Cough and cold symptoms, including sore throat		✓	
	Headache	✓		
	Rash		✓	
	Nausea		✓	
	Pneumonia		✓	✓
	Fever		✓	
	Abdominal pain	✓		
Uncommon	Tuberculosis		✓	✓
	Other serious infections		✓	✓
	Nerve disorder		✓	✓
	Appendicitis		✓	✓
	Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
	Bladder infection (painful urination)		✓	✓
	Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness)		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking HUMIRA, contact your/your child's doctor or pharmacist.

HOW TO STORE IT

Keep HUMIRA and all other medicines out of the reach of children.

Store between 2 and 8ºC (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE HUMIRA.** Protect from light. Refrigerated HUMIRA remains stable until the expiration date printed on the Pen or pre-filled syringe. Do not use beyond the expiration date.

When needed, for example when you/your child are travelling, a HUMIRA Pen or pre-filled syringe can be stored at room temperature (up to 25ºC/77ºF) for a single maximum period of 14 days.

Once taken out of the refrigerator for room temperature storage, a HUMIRA Pen or pre-filled syringe must be used within 14 days, even if it is put back in the refrigerator. If not used within 14 days, the HUMIRA Pen or pre-filled syringe must be discarded. You should record the date when the HUMIRA Pen or pre-filled syringe is first removed from the refrigerator.

Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

General Advice About Prescription Medicines

Talk to your/your child's doctor or other healthcare provider if you have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **CONSUMER INFORMATION** leaflet. If you have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you information about this medicine that was written for healthcare professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-866-8HUMIRA (1-866-848-6472).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

NOTE: Should you require information related to the management of side effects, contact your/your child's healthcare professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at 1-866-8HUMIRA (1-866-848-6472).

This leaflet was prepared by AbbVie Corporation.

Last revised: June 25, 2019

PART III: CONSUMER INFORMATION

PrHUMIRA®

40 mg/0.8 mL subcutaneous injection (Vial)
adalimumab

This leaflet is PART III of a three-part Product Monograph published when HUMIRA (Hu-MEER-ah) was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about HUMIRA. Contact the doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

HUMIRA treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of polyarticular juvenile idiopathic arthritis (JIA), pediatric Crohn's disease (CD) or pediatric uveitis and familiar with the HUMIRA efficacy and safety profile.

What the medication is used for:

HUMIRA is a medicine that is used in:

- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis, which is an inflammatory disease affecting one or more joints, with diagnosis typically occurring in children under the age of 16 years.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments. Crohn's disease is an inflammatory disease of the digestive tract.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients may be given other medicines for their disease before they are given HUMIRA. If you/your child do not respond well enough to these medicines, you/your child will be given HUMIRA to reduce the signs and symptoms of your/your child's disease.

What it does:

HUMIRA is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HUMIRA binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with polyarticular juvenile idiopathic arthritis or Crohn's disease have too much TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your/your child's joints or digestive tract. By binding to TNF-alpha, HUMIRA decreases the inflammation process of these diseases.

HUMIRA helps reduce the signs and symptoms of polyarticular juvenile idiopathic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's joints. In addition, HUMIRA helps reduce the signs and symptoms of pediatric Crohn's disease (such as abdominal pain and diarrhea). HUMIRA may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). HUMIRA may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease. HUMIRA helps control uveitis by reducing the risk of inflammation and loss of vision in pediatric patients. HUMIRA, however, can also lower your/your child's body's ability to fight infections. Taking HUMIRA can make you/your child more prone to getting infections or make any infection you/your child have worse.

When it should not be used:

You/your child should not take HUMIRA if you/your child have:

- an allergy to any of the ingredients in HUMIRA (see **What the important non-medicinal ingredients are** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). It is important that you tell the doctor if you/your child have symptoms of infections, e.g., fever, wounds, feeling tired, dental problems.
- moderate to severe heart failure (NYHA class III/IV).

What the medicinal ingredient is:

adalimumab

What the important non-medicinal ingredients are:

citric acid monohydrate, dibasic sodium phosphate dihydrate, mannitol, monobasic sodium phosphate dihydrate, polysorbate 80, sodium citrate, sodium chloride

For a full listing of non-medicinal ingredients, see PART I of the Product Monograph.

What dosage forms it comes in:

HUMIRA is available in a single-use, 1 mL vial containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL). All contents of the vial carton (including vial, accessories and packaging) are latex-free.

HUMIRA is also available in the following forms:
- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 10 mg adalimumab dissolved in 0.1 mL sterile solution (100 mg/mL) for pediatric use only

- Single-use, 1 mL pre-filled glass syringe containing 20 mg adalimumab dissolved in 0.2 mL sterile solution (100 mg/mL) for pediatric use only
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled Pen containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 80 mg adalimumab dissolved in 0.8 mL sterile solution (100 mg/mL)

WARNINGS AND PRECAUTIONS

Before starting, during and after treatment with HUMIRA, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect the immune system, HUMIRA can cause serious side effects. The possible serious side effects include:

Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or have difficulty breathing while taking HUMIRA, call the doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with HUMIRA. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and HUMIRA is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking HUMIRA or other TNF-blockers. Some patients receiving HUMIRA have developed types of cancer called non-melanoma skin cancer. Tell the doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take HUMIRA or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including HUMIRA, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on the cheeks or arms that gets worse in the sun, call the doctor right away. The doctor may decide to stop treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking HUMIRA or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes included tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact the doctor right away.

If you/your child received HUMIRA while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately 5 months after the last dose you/she received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her HUMIRA use during pregnancy so they can decide when your/her baby should receive any vaccine.

BEFORE you/your child start taking HUMIRA, you should tell the doctor if you/your child have or have had any of the following:

- any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from HUMIRA. If you are unsure, ask the doctor.
- a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- if you/your child have or ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms

of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call the doctor right away. The doctor will need to examine you/your child for tuberculosis and perform a skin test.
- if you/your child resided in or travelled to areas where there is a greater risk for certain kinds of infections, such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take HUMIRA, these may become active or more severe. If you don't know if you/your child have lived in an area where these infections are common, ask the doctor.
- if you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact the doctor immediately. These symptoms may occur several months after starting therapy with HUMIRA.
- if you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- if you/your child have or have had heart failure.
- if you/your child are scheduled to have major surgery or dental procedures.
- if you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up-to-date with all immunizations in agreement with current guidelines before starting HUMIRA.
- if you/your child are taking other medicines for you/your child's polyarticular juvenile idiopathic arthritis, you/your child's Crohn's disease or other conditions. You/your child can take other medicines provided the doctor has prescribed them, or has told you it is acceptable that you/your child take them while you/your child are taking HUMIRA. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking HUMIRA.
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

If you are not sure or have any questions about any of this information, ask the doctor.

INTERACTIONS WITH THIS MEDICATION

You/your child should not take HUMIRA with:

- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orencia®)
- anakinra (Kineret®)

If you have questions, ask the doctor.

PROPER USE OF THIS MEDICATION

HUMIRA is administered by injection under the skin (by subcutaneous injection).

Usual Dose:

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of HUMIRA is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of HUMIRA is 40 mg every other week.

For patients who require a full 40 mg dose of HUMIRA, a 40 mg Pen and 40 mg pre-filled syringe are also available.

Children, 13 to 17 years of age weighing ≥ 40 kg, with Crohn's disease:

- For children weighing ≥ 40 kg, the recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you/your child will begin a maintenance dose of 20 mg every other week. Depending on your/your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For the initial treatment or for an increase in dose to 40 mg, a 40 mg Pen and 40 mg pre-filled syringe are also available.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of HUMIRA is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of HUMIRA is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For the initial treatment or for an increase in dose to 40 mg, a 40 mg Pen and 40 mg pre-filled syringe are also available.

Overdose:

If you/your child accidentally inject HUMIRA more frequently than instructed, contact the doctor or local poison control centre right away.

Missed Dose:

If you forget to give yourself/your child an injection, you should inject the missed dose of HUMIRA as soon as you remember. Then administer your/your child's next dose as you would have on the originally scheduled date.

Administration:

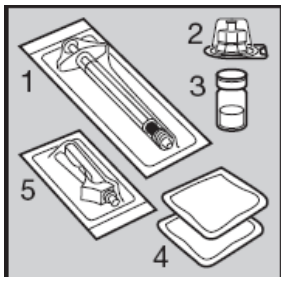
The following instructions explain how to inject HUMIRA. Please read the instructions carefully and follow them step-by-step. You will be instructed by your/your child's doctor or assistant or the AbbVie Care assistance program on the technique of injection and the amount to give yourself /your child. Do not attempt to give yourself/your child an injection until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person; for example, a healthcare professional, a family member or friend.

Failure to perform the following steps as described may cause contamination which may lead to an infection.

This injection should not be mixed in the same syringe with any other medicine.

Step 1. Setting Up

- Make sure you know the proper amount (volume) needed for dosing. If you don't know the amount, **STOP HERE** and contact the doctor for further instruction.
- You will need:
  - Two alcohol pads/swabs (not included in the HUMIRA carton)
  - A cotton ball or gauze pad
  - A special container for waste, such as a sharps container or as instructed by your/your child's nurse, doctor or pharmacist. Place the container on your work surface.
- Wash your hands thoroughly.
- Remove one box containing one syringe, one vial adapter, one vial and one needle from the carton. If there is a second box in the carton for a future injection, place it back in the refrigerator immediately.
- Look at the expiry date on the box to be used. **DO NOT** use any item after the date shown on the box.
- Set up the following items on a clean surface. **DO NOT** take them out of their individual packaging yet.
  - One 1mL syringe (1)
  - One vial adapter (2)
  - One vial of HUMIRA for injection (3)
  - Two alcohol pads (4)
  - One needle (5)



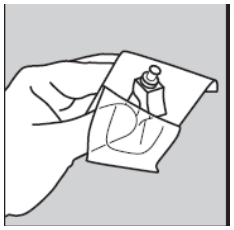
- If you do not have all of the pieces you need to give the injection, call the pharmacist. Use only the items provided in the box your/your child's HUMIRA prescription comes in (except for the alcohol pad/swab and cotton ball or gauze pad, which are not included in the HUMIRA carton).
- Make sure that the name HUMIRA appears on the vial label.
- Check the expiry date on the vial. Do not use the product if the date has passed the month and year shown.
- Make sure the liquid in the vial is clear and colourless. Do not use if the liquid is cloudy or discoloured or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing of the used needle and vial.

FOR YOUR/YOUR CHILD'S PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.

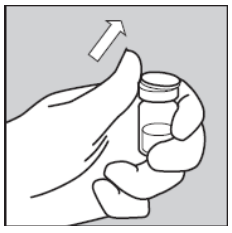
Step 2. Preparing the Dose for Injection

General Handling: **DO NOT** dispose of any waste items until after the injection is completed.

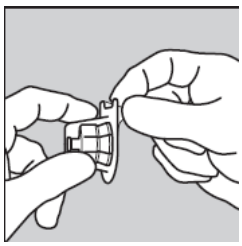
- Prepare the needle by partially peeling the package open from the end closest to the yellow syringe connector. Peel the package just far enough to expose the yellow syringe connector. Set the package down with the clear side of the package facing up.



- Pop off the white plastic cap from the vial to see the top of the vial stopper.



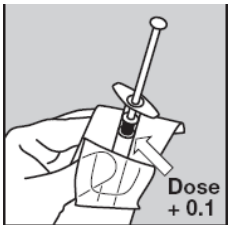
- Use one of the alcohol pads to wipe the vial stopper. **DO NOT** touch the vial stopper after wiping with the alcohol pad.
- Peel the cover off the vial adapter package but do not take out the vial adapter.



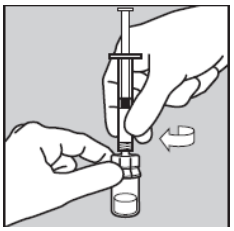
- Hold the vial with the vial stopper facing up.
- With the vial adapter still in the clear package, attach it to the vial stopper by pushing down until the vial adapter snaps in place.
- When you are sure the adapter is attached to the vial, lift off the package from the vial adapter.
- Gently set the vial with vial adapter down on your clean work surface. Be careful that it does not fall over. **DO NOT** touch the vial adapter.

- Prepare the syringe by partially peeling the package open from the end closest to the white plunger rod.
- Peel the clear package just far enough to expose the white plunger rod, but do not take the syringe out of the package.
- Hold the syringe package and **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose. For example, if the prescribed dose is 0.5 mL, pull the white plunger rod to 0.6 mL. **NEVER** pull past the 0.9 mL position regardless of the prescribed dose.
- You will set the volume to the prescribed dose in a later step.
- **DO NOT** pull the white plunger rod completely out of the syringe.

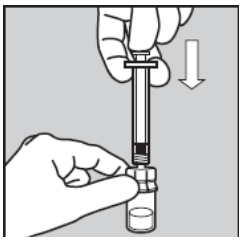
NOTE: If the white plunger rod is pulled completely out of the syringe, discard the syringe and contact your/your child's HUMIRA provider for a replacement. **DO NOT** try to reinsert the white plunger rod.



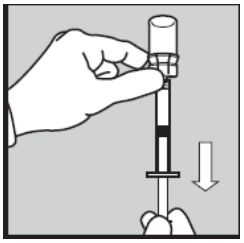
- **DO NOT** use the white plunger rod to remove the syringe from the package. Hold the syringe on the graduated area and pull the syringe from its package. **DO NOT** set the syringe down at any time.
- While holding the vial adapter firmly, insert the syringe tip into the vial adapter and twist the syringe clockwise with one hand until firm. **DO NOT** over-tighten.



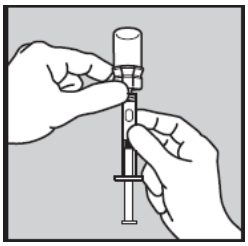
- While holding the vial, push the white plunger rod all the way down. This step is important to get the proper dose. Hold the white plunger rod in and turn the vial and syringe upside down.



- **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose. This is important to get the proper dose. You will set the volume to the prescribed dose in **Step 4. Preparing the Dose for Injection**. If the prescribed dose is 0.5 mL, pull the white plunger rod out to 0.6 mL. You will see the liquid medication from the vial go into the syringe.



- Push the white plunger rod all the way back in to push the liquid medication back into the vial. Again, **SLOWLY** pull the white plunger rod out to 0.1 mL beyond the prescribed dose. This is important to get the proper dose and important in order to prevent air bubbles or air gaps in the liquid medication. You will set the volume to the prescribed dose in **Step 4. Preparing the Dose for Injection**.

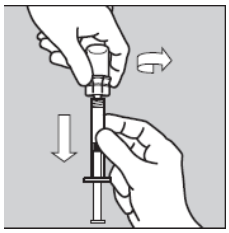


- If you see remaining air bubbles or air gaps in the liquid medication in the syringe, you may repeat this process up to three times. **DO NOT** shake the syringe.

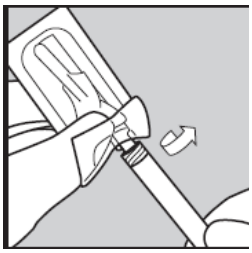
NOTE: If the white plunger rod is pulled completely out of the

syringe, discard the syringe and contact your/your child's HUMIRA provider for a replacement. **DO NOT** try to reinsert the white plunger rod.

- While still holding the syringe upright at the graduated area, remove the vial adapter with the vial by twisting the vial adapter off with the other hand. Be sure to remove the vial adapter with the vial from the syringe. **DO NOT** touch the tip of the syringe.



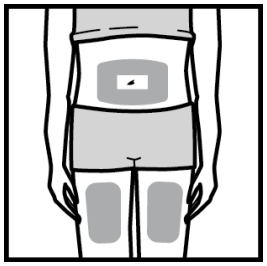
- If a large air bubble or air gap can be seen near the syringe tip, **SLOWLY** push the white plunger rod into the syringe until fluid begins to enter the syringe tip. **DO NOT** push the white plunger rod past the dose position.
- For example, if the prescribed dose is 0.5 mL, **DO NOT** push the white plunger rod past the 0.5 mL position.
- Check to see that the fluid remaining in the syringe is at least the prescribed dose volume. If the remaining volume is less than the prescribed dose volume, **DO NOT** use the syringe and contact your/your child's healthcare provider.
- With your free hand, pick up the needle package with the yellow syringe connector facing down.
- Keeping the syringe up, insert the syringe tip into the yellow syringe connector and twist the syringe as indicated by the arrow in the picture until firm. The needle is now attached to the syringe.



- Pull the needle package off, but **DO NOT** remove the clear needle cap.
- Place the syringe on your clean work surface. Continue with injection site and dose preparation immediately.

Step 3. Choosing and Preparing the Injection Site

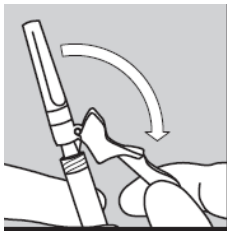
- Choose a site on the front of the thighs or abdomen. If you choose the abdomen, you should avoid the area two inches (5 cm) around the navel.
- Choose a different site each time you give yourself/your child an injection. Each new injection should be given at least one inch (2.5 cm) from a site you used before. **DO NOT** inject into areas where the skin is tender, bruised, red or hard or where there are scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.



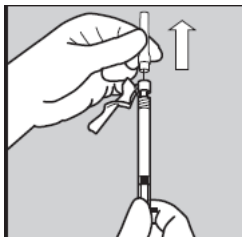
- Wipe the injection site where HUMIRA is to be injected with an alcohol pad (swab), using a circular motion. **DO NOT** touch this area again before giving the injection.

Step 4. Preparing the Dose for Injection

- Pick up the syringe with the needle pointing up.
- Use your other hand to flip the pink needle cover down toward the syringe.



- Remove the clear needle cap by pulling it straight up with your other hand.

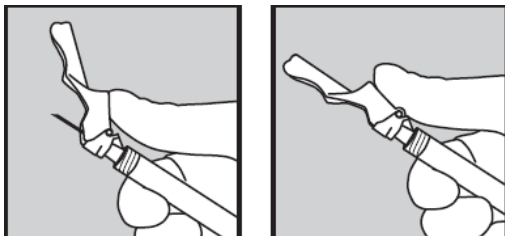


- The needle is clean.
  - **DO NOT** touch the needle.
  - **DO NOT** set the syringe down at any time after the clear needle cap is off.
  - **DO NOT** try to put the clear needle cap back on the needle.
- Hold the syringe at eye-level with the needle pointing up to see the amount clearly. Be careful not to squirt the liquid medication into your eye.
- Recheck the prescribed medication amount.
- Push the white plunger rod gently into the syringe until the syringe contains the prescribed amount of liquid. Excess liquid may come out of the needle while the white plunger rod is being pushed. **DO NOT** wipe off the needle or the syringe.

Step 5. Injecting HUMIRA

- With the free hand, gently grasp the cleaned area of skin and hold firmly.
- With the other hand, hold syringe at a 45-degree angle to the skin.
- With one quick, short motion, push the needle all the way into the skin.
- Let go of the skin in your hand.
- Push the white plunger rod to inject the liquid medication until the syringe is empty.
- When the syringe is empty, remove the needle from the skin, being careful to pull it out at the same angle as when it was inserted.

- Gently flip the pink needle cover up over the needle and snap into place, and set the syringe with the needle on the work surface.
- **DO NOT** put the clear needle cap back on the needle.



- Immediately press a cotton ball or gauze pad over the injection site and hold for 10 seconds. Slight bleeding may occur. **DO NOT** rub the injection site. A bandage is optional.
- Dispose of the syringe with the needle immediately into your special sharps container.

Step 6. Disposing of Supplies

- You should always check with the healthcare provider (e.g., doctor, nurse, or pharmacist) for instructions on how to properly dispose of used vials, needles and syringes. **DO NOT** use the same vial, vial adapter, needle and syringe more than once. You should follow any special provincial or local laws regarding the proper disposal of the syringe with needle, vial and vial adapter. **DO NOT throw the used syringe with needle, vial and vial adapter in the household trash or recycling bin**.
- Dispose of the used syringe with needle, vial and vial adapter in a container made especially for this purpose (sharps container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". **DO NOT** use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by the doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- The used alcohol pads and all other wrappers may be placed in the trash, unless otherwise instructed by the doctor, nurse or pharmacist. The cardboard carton may be recycled.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, HUMIRA can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell the doctor immediately if you/your child notice any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets

Tell the doctor as soon as possible if you/your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening psoriasis or a skin infection

- alopecia (loss of hair)
- changes in the colour of the skin
- worsening of the appearance of a scar
- night sweats
- weight loss

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
		Only if severe	In all cases	
Very Common (≥10%)	Injection site reaction		✓	
Common (≥1% and <10%)	Upper respiratory tract infections (including cold symptoms, such as sore throat and runny nose)		✓	✓
	Headache	✓		
	Rash		✓	
	Nausea		✓	
	Appendicitis		✓	✓
	Liver enzyme elevations		✓	✓
Uncommon (≥0.1% and <1%)	Tuberculosis		✓	✓
	Other serious infections		✓	✓
	Nerve disorder (including symptoms such as numbness or tingling, problems with vision, weakness in arms or legs and dizziness)		✓	✓
	Herpes simplex (cold sores)		✓	✓
	Pneumonia (lung infection with symptoms such as cough, fever and chest pain)		✓	✓
	Bronchopneumonia (lung infection with symptoms such as cough, fever and chest pain)		✓	✓
	Streptococcal pharyngitis (throat infection with symptoms such as sore throat and fever)		✓	✓
	Low white blood cell count		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking HUMIRA, contact the doctor or pharmacist.

HOW TO STORE IT

Keep HUMIRA and all other medicines out of the reach of children.

Store between 2 and 8ºC (in a refrigerator) in the original container until ready to use. **DO NOT FREEZE HUMIRA.** Protect from light. Refrigerated HUMIRA remains stable until the expiration date printed on the vial. Do not use beyond the expiration date.

General Advice About Prescription Medicines

Talk to the doctor or other healthcare provider if you have any questions about this medicine or your/your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **CONSUMER INFORMATION** leaflet. If you have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you information about this medicine that was written for healthcare professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-866-8HUMIRA (1-866-848-6472).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

NOTE: Should you require information related to the management of side effects, contact your/your child's healthcare professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at 1-866-8HUMIRA (1-866-848-6472).

This leaflet was prepared by AbbVie Corporation.

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