PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]HUMIRA® (pronounced Hu-MEER-ah)

adalimumab injection

40 mg/0.8 mL sterile solution (50 mg/mL) subcutaneous injection (Pre-filled syringe/Pen)

Read this carefully before you start taking **Humira** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Humira**.

If your child is taking Humira, all of the information in this PATIENT MEDICATION INFORMATION applies to them. As their caregiver, please read this information before they start taking Humira. Talk to your child's healthcare professional if you need any additional information on their condition and treatment.

Serious Warnings and Precautions

Before starting, during and after treatment with Humira, you 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 immune system, Humira can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you develop a severe rash, swollen face or difficulty breathing while taking Humira, call your 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 doctor if you 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 take Humira or other TNF-blockers, your 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 have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that gets worse in the sun, call your doctor right away. Your doctor may decide to stop your 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 could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your 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 develop symptoms such as persistent fever, bleeding, or bruising, you should contact your doctor right away.

What is Humira 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.
- children 5 to 17 years of age who have ulcerative colitis.

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 have Crohn's disease, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Humira to reduce the signs and symptoms of your disease.

How does Humira work?

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 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 ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your 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 adult and pediatric 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 or ulcerative colitis.

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 body's ability to fight infections. Taking Humira can make you more prone to getting infections or make any infection you have worse.

What are the ingredients in Humira?

Medicinal ingredient: adalimumab

Non-medicinal ingredients: citric acid monohydrate, dibasic sodium phosphate dihydrate, mannitol, monobasic sodium phosphate dihydrate, polysorbate 80, sodium citrate, sodium chloride, sodium hydroxide (added as necessary to adjust pH), and water for injection

Humira comes in the following dosage 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)

Do not use Humira if:

You should not take Humira if you have:

- an allergy to any of the ingredients in Humira (see What are the ingredients in Humira? 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)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Humira. Talk about any health conditions or problems you may have, including if:

- you have or have had any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from Humira. If you are unsure, ask your doctor.

- you have a history of infections that keep coming back or other conditions that might increase your risk of infections, including fungal infections.

- you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats), call your doctor right away. Your doctor will need to examine you for tuberculosis and perform a skin test.

- you 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 bacteria or a fungus that can affect the lungs or other parts of your body. If you take Humira, these may become active or more severe. If you don’t know if you have lived in or travelled to an area where these infections are common, ask your doctor.

- you 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 experience any of these signs and symptoms, contact your doctor immediately. These symptoms may occur several months after starting therapy with Humira.

- you experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome.

- you have or have had heart failure.

- you are scheduled to have major surgery or dental procedures.

- you 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 are taking other medicines for your rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, psoriasis, or other conditions. You can take other medicines provided your doctor has prescribed them or has told you it is acceptable that you take them while you are taking Humira. It is important that you tell your doctor about any other medicines you are taking for other conditions (for example, high blood pressure medicine) before you start taking Humira.

- you are taking other medicines for your Crohn’s disease or other conditions. You can take other medicines provided your doctor has prescribed them or has told you it is acceptable that you take them while you are taking Humira. It is important that you tell the doctor about any other medicines you are taking for other conditions before you start taking Humira.

- you are taking any over-the-counter drugs, herbal medicines, and vitamin and mineral supplements.

- you are pregnant or could become pregnant.
- you are breastfeeding or plan to breastfeed.

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

Other warnings you should know about:

If you received Humira while pregnant, your 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 baby's doctors and other healthcare professionals about your Humira use during pregnancy so they can decide when your baby should receive any vaccine.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Humira:

You 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 doctor.

How to take Humira:

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 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 will begin a maintenance dose of 20 mg every other week. Depending on your 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 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 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.

Children, from 5 to 17 years of age with Ulcerative Colitis:

- weighing less than 40 kg: the induction dose of Humira is 80 mg at Week 0, followed by 40 mg at Week 2. The recommended Humira maintenance dose regimen is 40 mg every other week or 20 mg every week beginning at Week 4.

- weighing 40 kg or more: the induction dose of Humira is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended Humira maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

Overdose:

If you think you, or a person you are caring for, have taken too much Humira, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using Humira?

These are not all the possible side effects you may feel when taking Humira. If you experience any side effects not listed here, contact your healthcare professional.

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 doctor immediately if you 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 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 urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Injection site reaction		✓	
COMMON			
Cough and cold symptoms, including sore throat		✓	
Headache	✓		
Rash		✓	
Nausea		✓	
Pneumonia		✓	✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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)		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

General Advice About Prescription Medicines

Talk to your doctor or other healthcare provider if you have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION 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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep Humira and all other medicines out of the reach and sight of children.

Store between 2 and 8°C (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 are travelling, a Humira Pen or pre-filled syringe can be stored at room temperature (up to 25°C/77°F) 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.

If you want more information about Humira:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (www.abbvie.ca), or by calling 1-866-8HUMIRA (1-866-848-6472).

This leaflet was prepared by AbbVie Corporation.

Last Revised: SEP 16, 2022

Instructions for Use
PrHUMIRA®
(adalimumab injection)
Pre-filled syringe/Pen

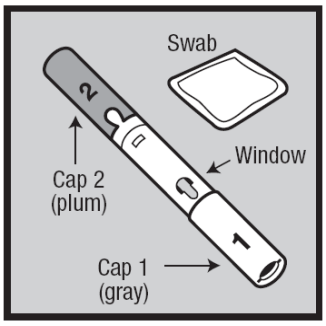
The following instructions explain how to inject Humira. Please read the instructions carefully and follow them step-by-step. You will be instructed by your doctor or assistant on the technique of injection. Do not attempt to inject until you are sure that you understand how to prepare and give the injection. 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 if you require assistance with injections should you prefer nurse-administered injections.

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

Step 1. Setting Up

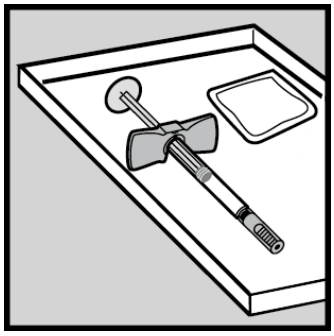
- You will need one alcohol pad/swab and a cotton ball or gauze pad (not included in the Humira carton).
- Remove one dose tray containing a Humira Pen or pre-filled syringe from the box in the refrigerator.
    - Do not shake or drop the Pen or pre-filled syringe.
    - Do not use the Pen or pre-filled 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)



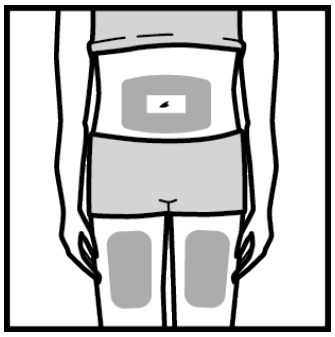
- If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your Humira prescription comes in (except for the alcohol pad/swab and cotton ball or gauze pad, which are not included in the Humira carton).

- 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 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 thighs or abdomen. If you choose your abdomen, you should avoid the area two inches around your navel.
- Choose a different site each time you give yourself 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 have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.

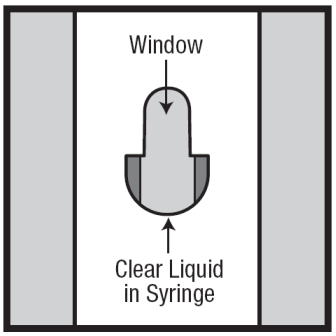


- Wipe the injection site where Humira is to be injected with an alcohol pad (swab), using a circular motion. Do **NOT** touch this area again before giving the injection.

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.

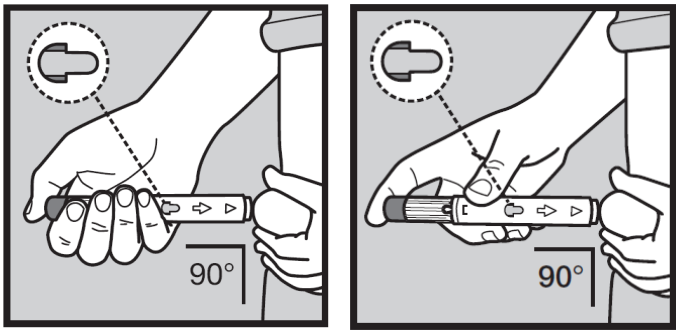
Step 4. Injecting Humira

Humira Pen

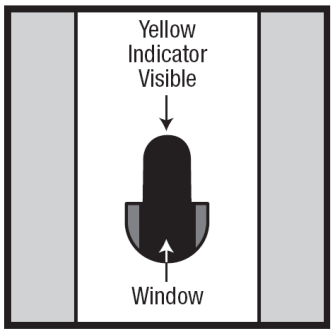
- Only remove the caps **immediately** before injection.
- Hold the gray body of the Pen with one hand.
    - Place your hand on the middle of the Pen so that neither the gray cap (Cap 1) nor the plum cap (Cap 2) is covered.
    - Hold the Pen with the gray cap (Cap 1) pointing up.
- With your other 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.

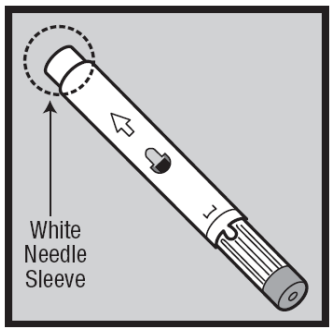
- Please note that the Pen is activated after removing Cap 2 and that pressing the button under Cap 2 will immediately result in discharge of medication.
- Do not press the plum-coloured activation button until properly positioned.
- **DO NOT RECAP as this could cause the unit to discharge.**

- 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 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 from touching the needle.



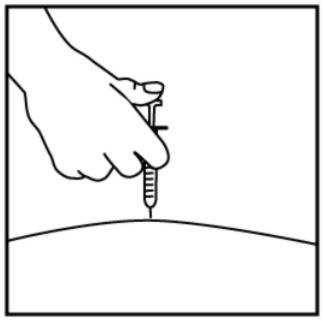


- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you have slight bleeding, this is normal.

- Dispose of the Pen immediately into your special sharps container.

<u>Humira Pre-Filled Syringe</u>

- 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 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 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 doctor, nurse or pharmacist. The dose tray and cover may be recycled.

This leaflet was prepared by AbbVie Corporation.

Last Revised: SEP 16, 2022

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]HUMIRA® (pronounced Hu-MEER-ah)

adalimumab injection

10 mg/0.1 mL sterile solution (100 mg/mL) subcutaneous injection (Pre-filled syringe)*

20 mg/0.2 mL sterile solution (100 mg/mL) subcutaneous injection (Pre-filled syringe)*

40 mg/0.4 mL sterile solution (100 mg/mL) subcutaneous injection (Pre-filled syringe/Pen)

80 mg/0.8 mL sterile solution (100 mg/mL) subcutaneous injection (Pre-filled syringe/Pen)

***For pediatric use only**

Read this carefully before you start taking **Humira** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Humira**.

If your child is taking **Humira**, all of the information in this **PATIENT MEDICATION INFORMATION** applies to them. As their caregiver, please read this information before they start taking **Humira**. Talk to your child's healthcare professional if you need any additional information on their condition and treatment.

Serious Warnings and Precautions

Before starting, during and after treatment with Humira, you 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 immune system, Humira can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you develop a severe rash, swollen face or difficulty breathing while taking Humira, call your 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 doctor if you 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 take Humira or other TNF-blockers, your 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 have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that gets worse in the sun, call your doctor right away. Your doctor may decide to stop your 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 could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your 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 develop symptoms such as persistent fever, bleeding, or bruising, you should contact your doctor right away.

What is Humira 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.
- children 5 to 17 years of age who have ulcerative colitis.

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 have Crohn's disease, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Humira to reduce the signs and symptoms of your disease.

How does Humira work?

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 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 ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your 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 adult and pediatric 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 or ulcerative colitis.

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 body's ability to fight infections. Taking Humira can make you more prone to getting infections or make any infection you have worse.

What are the ingredients in Humira?

Medicinal ingredient: adalimumab

Non-medicinal ingredients: mannitol, polysorbate 80, and water for injection

Humira comes in the following dosage 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)

Do not use Humira if:

You should not take Humira if you have:

- an allergy to any of the ingredients in Humira (see What are the ingredients in Humira? 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)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Humira. Talk about any health conditions or problems you may have, including if:

- you have or have had any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from Humira. If you are unsure, ask your doctor.

- you have a history of infections that keep coming back or other conditions that might increase your risk of infections, including fungal infections.

- you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Your doctor will need to examine you for tuberculosis and perform a skin test.

- you 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 bacteria or a fungus that can affect the lungs or other parts of your body. If you take Humira, these may become active or more severe. If you don’t know if you have lived in or travelled to an area where these infections are common, ask your doctor.

- you 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 experience any of these signs and symptoms, contact your doctor immediately. These symptoms may occur several months after starting therapy with Humira.

- you experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome.

- you have or have had heart failure.

- you are scheduled to have major surgery or dental procedures.

- you 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 are taking other medicines for your rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, psoriasis, or other conditions. You can take other medicines provided your doctor has prescribed them or has told you it is acceptable that you take them while you are taking Humira. It is important that you tell your doctor about any other medicines you are taking for other conditions (for example, high blood pressure medicine) before you start taking Humira.

- you are taking other medicines for your Crohn's disease or other conditions. You can take other medicines provided your doctor has prescribed them or has told you it is acceptable that you take them while you are taking Humira. It is important that you tell the doctor about any other medicines you are taking for other conditions before you start taking Humira.

- you are taking any over-the-counter drugs, herbal medicines, and vitamin and mineral supplements.

- you are pregnant or could become pregnant.

- you are breastfeeding or plan to breastfeed.

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

Other warnings you should know about:

If you received Humira while pregnant, your 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 baby's doctors and other healthcare professionals about your Humira use during pregnancy so they can decide when your baby should receive any vaccine.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Humira:

You 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 doctor.

How to take Humira:

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 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 will begin a maintenance dose of 20 mg every other week. Depending on your 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 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 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.

Children, from 5 to 17 years of age with Ulcerative Colitis:

- weighing less than 40 kg: the induction dose of Humira is 80 mg at Week 0, followed by 40 mg at Week 2. The recommended Humira maintenance dose regimen is 40 mg every other week or 20 mg every week beginning at Week 4.

- weighing 40 kg or more: the induction dose of Humira is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended Humira maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

Overdose:

If you think you, or a person you are caring for, have taken too much Humira, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using Humira?

These are not all the possible side effects you may feel when taking Humira. If you experience any side effects not listed here, contact your healthcare professional.

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 doctor immediately if you 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 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 urine (dark or red)
- worsening of the appearance of a scar

- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	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)		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

General Advice About Prescription Medicines

Talk to your doctor or other healthcare provider if you have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION 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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep Humira and all other medicines out of the reach and sight of children.

Store between 2 and 8°C (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 are travelling, a Humira Pen or pre-filled syringe can be stored at room temperature (up to 25°C/77°F) 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.

If you want more information about Humira:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (www.abbvie.ca), or by calling 1-866-8HUMIRA (1-866-848-6472).

This leaflet was prepared by AbbVie Corporation.

Last Revised: SEP 16, 2022

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Instructions for Use
PrHUMIRA®
(adalimumab injection)
Pre-filled syringe/Pen

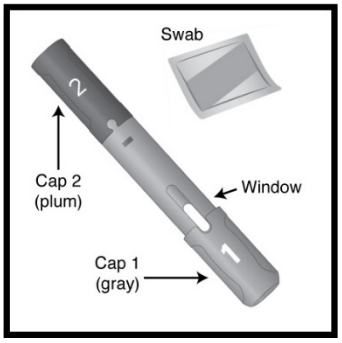
The following instructions explain how to inject Humira. Please read the instructions carefully and follow them step-by-step. You will be instructed by your doctor or assistant on the technique of injection. Do not attempt to inject until you are sure that you understand how to prepare and give the injection. 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 if you require assistance with injections should you prefer nurse-administered injections.

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

Step 1. Setting Up

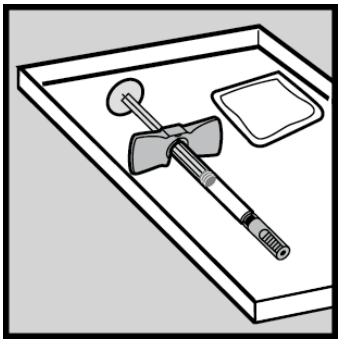
- You will need one alcohol pad/swab and a cotton ball or gauze pad (not included in the Humira carton).
- Remove one dose tray containing a Humira Pen or pre-filled syringe from the box in the refrigerator.
    - Do not shake or drop the Pen or pre-filled syringe.
    - Do not use the Pen or pre-filled 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)

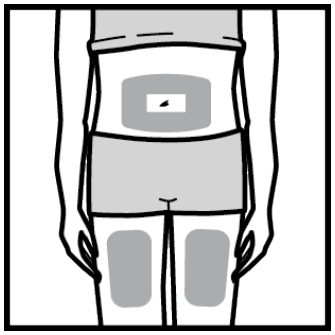


- If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your Humira prescription comes in (except for the alcohol pad/swab and cotton ball or gauze pad, which are not included in the Humira carton).
- Make sure that the 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 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 thighs or abdomen. If you choose your abdomen, you should avoid the area two inches around your navel.
- Choose a different site each time you give yourself 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 have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.

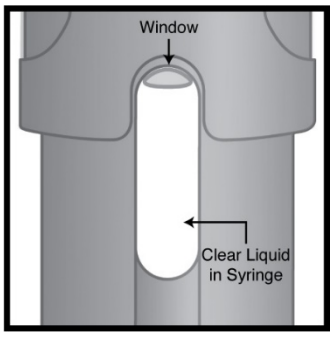


- Wipe the injection site where Humira is to be injected with an alcohol pad (swab), using a circular motion. Do NOT touch this area again before giving the injection.

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

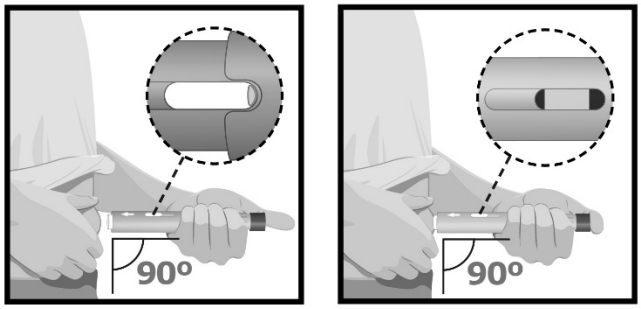
- Only remove the caps **immediately** before injection.

- 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.

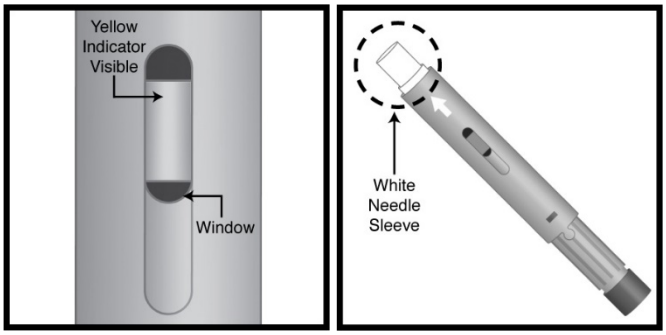
    - Hold the Pen with the gray cap (Cap 1) pointing up.

- 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 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 from touching the needle.

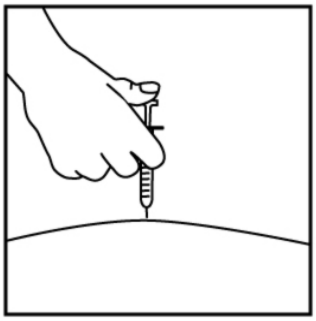


- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you have slight bleeding, this is normal.

- 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 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 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 doctor, nurse or pharmacist. The dose tray and cover may be recycled.

This leaflet was prepared by AbbVie Corporation.

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