

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

SKYRIZI™

risankizumab injection

75 mg in 0.83 mL sterile solution (90 mg/mL) subcutaneous injection

Read this carefully before you start taking SKYRIZI 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 SKYRIZI.

What is SKYRIZI used for?

SKYRIZI is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body.

How does SKYRIZI work?

SKYRIZI contains the active substance risankizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation. It also improves skin clearance and reduces symptoms of psoriasis such as burning, itching, pain, and redness.

What are the ingredients in SKYRIZI?

Medicinal ingredients: risankizumab

Non-medicinal ingredients: disodium succinate hexahydrate, polysorbate 20, sorbitol, succinic acid, and water for injection

SKYRIZI comes in the following dosage forms:

Pre-filled syringe with 75 mg of risankizumab in 0.83 mL of solution for injection (90 mg/mL).

SKYRIZI is a clear and colourless to slightly yellow liquid in a pre-filled syringe with needle guard. Each carton contains 2 pre-filled syringes.

Do not use SKYRIZI if:

- You are allergic to risankizumab or any of the other ingredients of this medicine. See **What are the ingredients in SKYRIZI?**

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

- you currently have an infection or if you have an infection that keeps coming back. SKYRIZI may lower your ability to fight infections and may increase your risk of infections.
- you have tuberculosis (TB) or have been in close contact with someone with TB.
- you have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called 'live vaccines') while using SKYRIZI.

Talk to your healthcare professional right away if you have any of the symptoms of serious infection:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- cough
- blood in your phlegm (mucus)
- warm, red or painful skin, sores on your body different from your psoriasis, or a painful skin rash with blisters
- muscle aches
- weight loss

Talk to your healthcare professional right away if you have any of the signs or symptoms of an allergic reaction, including:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Other warnings you should know about:

SKYRIZI is not approved for children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if SKYRIZI can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using SKYRIZI and for at least 20 weeks after the last SKYRIZI dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if SKYRIZI passes into breast milk. You and your doctor should decide if you will breastfeed while using SKYRIZI.

Tell your healthcare professional about all the medicines you are using, have recently used or might use, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take SKYRIZI:

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure how to use this medicine.

SKYRIZI is given as 2 injections under your skin (called “subcutaneous injections”).

You and your doctor, pharmacist or nurse will decide if you should inject SKYRIZI yourself. Do not inject yourself with this medicine unless you have been trained by your doctor, pharmacist or nurse. A caregiver may also give your injections after training. The AbbVie Care patient assistance program is also available to you if you require assistance with injections should you prefer nurse-administered injections.

For a more comfortable injection: Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.

Read the “**Instructions for Use**” before injecting SKYRIZI yourself.

Usual Dose:

The dose is 150 mg given as two 75 mg injections.

	How much?	When?
1st dose	150 mg (two 75 mg injections)	When your doctor tells you
2nd dose	150 mg (two 75 mg injections)	4 weeks after 1 st dose
Further doses	150 mg (two 75 mg injections)	Every 12 weeks starting after 2 nd dose

Do not stop using SKYRIZI without talking to your doctor first. If you stop treatment, your symptoms may come back.

Overdose:

If you have used more SKYRIZI than you should or the dose has been given sooner than prescribed, talk to your doctor.

If you think you have taken too much SKYRIZI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forgot to use SKYRIZI, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Talk to your doctor if you are not sure what to do.

What are possible side effects from using SKYRIZI?

These are not all the possible side effects you may feel when taking SKYRIZI. If you experience any side effects not listed here, contact your doctor. Your doctor will decide if you can keep using SKYRIZI.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common: may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache
- itching
- burning when you urinate or urinating more often than normal

Uncommon: may affect up to 1 in 100 people

- small raised red bumps on the skin

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	
Uncommon			
Serious Infections: Fever, flu-like symptoms, night sweats, cough, blood in your phlegm (mucus), warm, red or painful skin, muscle aches, weight loss		√	√

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 doctor, pharmacist or nurse.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 this medicine out of reach and sight of children.

Do not use this medicine after the expiration date which is stated on the syringe label and outer carton after 'EXP'.

Store in a refrigerator between 2 to 8 °C (36 to 46 °F). Do not freeze. Do not use if SKYRIZI has been frozen.

Keep the pre-filled syringes in the original carton in order to protect from light.

The liquid should look clear to slightly yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

This medicine is for single use only. Ask your doctor, pharmacist or nurse how to throw away used syringes safely.

If you want more information about SKYRIZI:

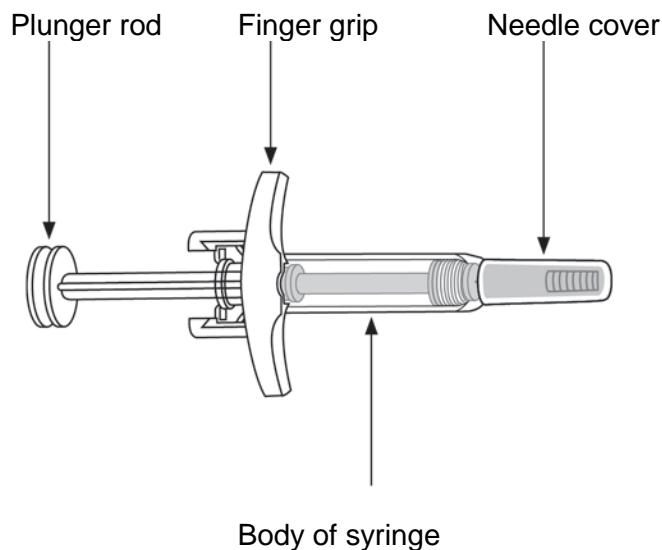
- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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Instructions for Use
SKYRIZI™
(risankizumab injection)
Pre-filled syringe

Please read complete instructions before using SKYRIZI.



Important information to know before you inject SKYRIZI

- If your doctor decides that you or a caregiver may be able to give your injections at home, you and your caregiver should receive training on how to inject SKYRIZI before giving an injection. Injections should be given in the thighs or abdomen. Caregivers can also give SKYRIZI in the upper outer arm. Talk to your doctor, pharmacist or nurse if you need help. The AbbVie Care patient assistance program is also available to you if you require assistance with injections should you prefer nurse-administered injections.
- Mark the dates on your calendar so you know when to next use SKYRIZI.
- Keep SKYRIZI in the original carton to protect from light until it is time to use it.
- **Do not** inject if the liquid is cloudy or contains flakes or large particles. The liquid should look clear to slightly yellow and may contain tiny white or clear particles.
- **Do not** use if the expiry date (EXP) has passed.
- **Do not** use if the liquid has been frozen (even if thawed).
- **Do not** use if the syringe has been dropped or damaged.
- **Do not** use if the syringe tray cover is broken or missing. Return this medicine to the pharmacy.
- **Do not** remove the needle cover until just before the injection.

For a more comfortable injection: Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.

- **Do not** remove the syringes from the carton until ready to inject.
- **Do not** warm SKYRIZI in any other way. For example, **do not** warm it in a microwave or in hot water.

Storage Information

Store in refrigerator between 2 to 8 °C (36 to 46 °F). Do not freeze. Keep SKYRIZI out of reach and sight of children. Keep SKYRIZI pre-filled syringe in the original carton to protect from light.

Follow the steps below each time you use SKYRIZI

Prepare for Injection

STEP 1



You will need these supplies:

- 2 pre-filled syringes

Not provided in the SKYRIZI carton:

- 2 alcohol pads
- 2 cotton balls or gauze pads
- Special disposal container.

Place these items on a clean, flat surface.

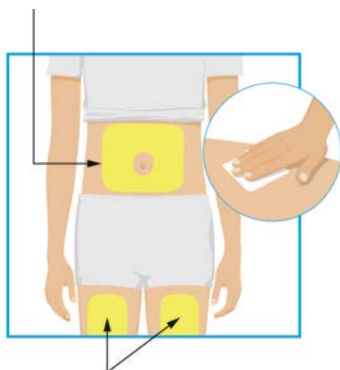
Wash and dry your hands.

Start with one syringe for the first injection.

For a full dose, 2 injections are required, one after the other.

STEP 2

Areas to inject



Areas to inject

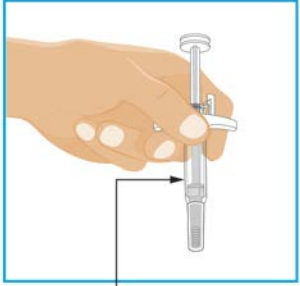
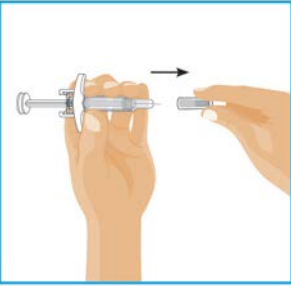
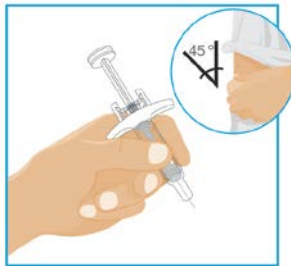
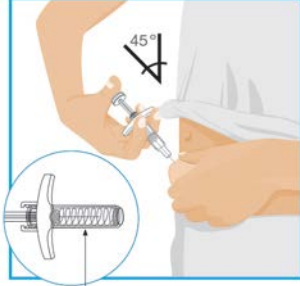
Choose from these 3 areas to inject:

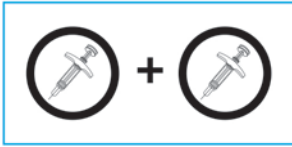
- front of left thigh or right thigh
- belly (abdomen) at least 5 cm (2 inches) from the belly button (navel)

For the second syringe, inject at least 3 cm (1 inch) away from the first injection. **Do not** inject into the same place.

Before each injection, wipe where you will inject in a circular motion with an alcohol pad.

- **Do not** inject through clothes.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks.
- **Do not** inject into areas affected by psoriasis.

<p>STEP 3</p>  <p>Check liquid</p>	<p>Hold the syringe with covered needle pointing down, as shown.</p> <p>Check the liquid in the syringe.</p> <ul style="list-style-type: none"> • It is normal to see bubbles in the window. • The liquid should look clear to slightly yellow and may contain tiny white or clear particles. • Do not use if the liquid is cloudy or contains flakes or large particles.
<p>STEP 4</p> 	<p>Removing the needle cover:</p> <ul style="list-style-type: none"> • Hold the syringe in one hand. • With the other hand, gently pull the needle cover straight off. • You may see a drop of liquid at the end of the needle. This is normal. • Throw away the needle cover. • Do not touch the needle with your fingers or let the needle touch anything.
<p>Inject SKYRIZI</p>	
<p>STEP 5</p> 	<p>Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.</p> <p>Gently pinch the area of cleaned skin with your other hand and hold it firmly.</p> <p>Insert the needle all the way into the skin at about a 45-degree angle using a quick, short movement. Keep the syringe steady at the same angle.</p>
<p>STEP 6</p>  <p>Needle guard</p>	<p>Slowly push the plunger all the way in until all of the liquid is injected.</p> <p>Pull the needle out of the skin while keeping the syringe at the same angle.</p> <p>Slowly take your thumb off the plunger. The needle will then be covered by the needle guard.</p> <ul style="list-style-type: none"> • The needle guard will not activate unless all the liquid is injected. • Speak to your doctor, pharmacist or nurse if you think you have not given a full dose. <p>Press a cotton ball or gauze pad where you have injected and hold for 10 seconds.</p> <p>Do not rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal.</p>

STEP 7

For a full dose, two injections are needed, one after the other.

- Repeat Steps 2 through 6 with the second syringe.
- Inject the second syringe immediately after the first injection.

After your Injection**STEP 8**

Throw away used syringes in a special disposal container.

- **Do not** throw away used syringes in the household waste.
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container.

Need Help?

Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer's website (www.abbvie.ca) or call 1-888-704-8271.

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