

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Skyrizi?

Skyrizi contains the active ingredient risankizumab. Skyrizi is used to treat adults with moderate to severe plaque psoriasis.

For more information, see Section [1. Why am I using Skyrizi?](#) in the full CMI.

### 2. What should I know before I use Skyrizi?

Check the list of ingredients at the end of the CMI. Do not use Skyrizi if you have ever had an allergic reaction to any of them.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Skyrizi?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Skyrizi and affect how it works or Skyrizi may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Skyrizi?

- Skyrizi is injected under the skin. More instructions can be found in Section [4. How do I use Skyrizi?](#) in the full CMI.

### 5. What should I know while using Skyrizi?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Ensure you are up to date with your immunisations <u>before</u> you start therapy with Skyrizi.</li><li>Speak to your doctor if you think you have an infection.</li><li>Remind any doctor, dentist or pharmacist you visit that you are using Skyrizi.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine or change the dose without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Skyrizi is not expected to have any effect on your ability to drive or use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>There is no information on the effects of using Skyrizi with alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store Skyrizi in the refrigerator at 2°C to 8°C. Do not freeze.</li><li>Keep it in the original carton until it's time to inject it to protect it from light.</li></ul>

For more information, see Section [5. What should I know while using Skyrizi?](#) in the full CMI.

### 6. Are there any side effects?

The more serious side effects include: Symptoms of a serious infection, including fever, flu-like symptoms, night sweats, feeling tired or short of breath, a cough that won't go away, warm, red, painful skin or painful rash with blisters.

The more common side effects include: upper respiratory infections with symptoms such as sore throat and stuffy nose, tiredness, headache, injection site reactions, itching, fungal skin infection.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# SKYRIZI® (sky-ri-zee)

Active ingredient: *risankizumab* (ri-zan-ki-zyu-mab)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Skyrizi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Skyrizi.**

Where to find information in this leaflet:

1. [Why am I using Skyrizi?](#)
2. [What should I know before I use Skyrizi?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Skyrizi?](#)
5. [What should I know while using Skyrizi?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I using Skyrizi?

Skyrizi contains the active ingredient risankizumab which is a type of protein called a monoclonal antibody. It works by stopping a protein in the body called IL-23 which causes inflammation.

Skyrizi is used to treat adults with moderate to severe plaque psoriasis by reducing the inflammation. Skyrizi improves skin clearance and the appearance of the nails. It also reduces the symptoms of psoriasis such as burning, itching, pain, redness and scaling.

### 2. What should I know before I use Skyrizi?

#### Warnings

**Do not use Skyrizi if:**

1. you are allergic to risankizumab, or any of the ingredients listed at the end of this leaflet.
2. you have an infection considered by your doctor to need special attention.

**Check with your doctor if you:**

- have an infection now
- have had an infection that keeps coming back
- have or have had tuberculosis
- have had a recent vaccination or are scheduled for any immunisations
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or plan to do so.

### Children

- Skyrizi is not recommended for children younger than 18 years.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do this even though Skyrizi is not expected to be affected by other medicines, nor is it expected to interfere with other medicines.

### 4. How do I use Skyrizi?

#### How much to use

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

1. Inject two 75 mg injections on the first day;
2. Inject two 75 mg injections on the same day 4 weeks later (Week 4);
3. Inject two 75 mg injections on the same day 12 weeks later (Week 16);
4. Continue injecting two 75 mg injections on the same day every 12 weeks.

Follow all the instructions given to you and continue to use Skyrizi until your doctor tells you to stop.

#### How to inject Skyrizi

- Skyrizi is injected under the skin (subcutaneous injection).
- It can be injected by the patient or by someone else, such as a family member, friend or carer.
- An injection should not be attempted until proper training has been received on the correct injection technique.
- Read the instructions for preparing and giving a Skyrizi injection that are supplied with the product.

[Click on the link for the instructions on how to inject 75 mg/0.83mL pre-filled syringe:](#)

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Skyrizi.

#### If you forget to inject Skyrizi

It is important that you use your medicine as instructed.

If you miss your dose at the usual time, inject Skyrizi as soon as you remember, and continue injecting the next dose at the usual time on your next scheduled day.

**Do not inject a double dose to make up for the dose you missed.**

### If you inject too much Skyrizi

**You should immediately:**

- phone the Poisons Information Centre in Australia (**by calling 13 11 26**), in New Zealand the National Poisons Centre (by calling 0800 POISON or 0800 764 766) or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there appear to be no signs of discomfort or poisoning.**

## 5. What should I know while using Skyrizi?

### Things you should do

- Ensure you are up to date with your immunisations before you start therapy with Skyrizi
- Keep all your doctor's appointments so your progress can be tracked.

### Call your doctor straight away if you:

- Have symptoms of an infection, such as fever, flu-like symptoms, night sweats.
- Feeling tired or short of breath and have a cough that will not go away.
- Become pregnant while using Skyrizi.

Remind any doctor or dentist you visit that you are using Skyrizi.

### Things you should not do

- Do not inject Skyrizi if the liquid looks cloudy or contains flakes or large particles.
- Do not stop using this medicine or change the dose without checking with your doctor.

### Driving or using machines

Skyrizi is not expected to have any effect on your ability to drive or use machines.

### Drinking alcohol

There is no information on the effects of using Skyrizi with alcohol.

### Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

- Keep Skyrizi in the refrigerator (at 2°C to 8°C). Do not freeze.
- Keep the syringe in the carton to protect it from light.

The syringe can be taken out of the fridge 15 to 30 minutes before injected, provided it is kept in the carton. This may make the injection more comfortable.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

### When to discard your medicine

Throw away the used syringe immediately after injecting, as instructed by your doctor or nurse.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Upper respiratory tract infection:</b></p> <ul style="list-style-type: none"><li>• sore throat</li><li>• stuffy nose</li></ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"><li>• fungal skin infection, such as athlete's foot (tinea)</li><li>• pain, or redness at the injection site</li><li>• small raised red bumps on the skin</li></ul> <p><b>General:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• feeling especially tired</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### More serious side effects

More serious side effects	What to do
<p><b>Signs of a serious infection:</b></p> <ul style="list-style-type: none"><li>• fever</li><li>• flu-like symptoms</li><li>• night sweats</li><li>• feeling tired or short of breath</li><li>• cough that won't go away</li><li>• warm, red painful skin</li><li>• painful skin rash with small red blisters</li></ul>	<p><b>Call your doctor straight away, if you notice any of these serious side effects.</b></p>

**Very serious side effects**

Very serious side effects	What to do
<b>Signs of an allergic reaction:</b> <ul style="list-style-type: none"> <li>• difficulty breathing or swallowing</li> <li>• swelling of face, lips, tongue or throat</li> <li>• severe itching of skin, with a red rash or raised bumps</li> </ul>	<b>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b>

This leaflet was prepared in March 2021.

Version 2

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Skyrizi contains

<b>Active ingredient (main ingredient)</b>	risankizumab
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• sodium succinate hexahydrate</li> <li>• succinic acid</li> <li>• sorbitol</li> <li>• polysorbate 20</li> <li>• water for injections</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

Skyrizi contains 34 mg sorbitol in each 75 mg/0.83mL injection.

### What Skyrizi looks like

Skyrizi is a colourless to slightly yellow liquid and is supplied in a prefilled syringe with needle guard. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles. Two syringes are supplied per carton. The carton also contains two alcohol pads.

### Who distributes Skyrizi?

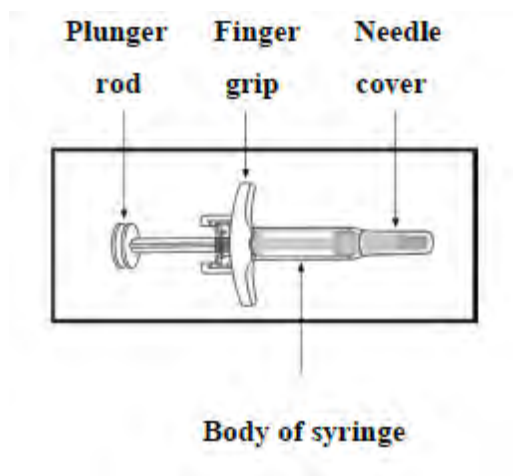
SKYRIZI is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria Street

Wellington 6011

## Instructions for Use



### Important information to know before you inject SKYRIZI.

- SKYRIZI is for single use in one patient only. Discard any residue.
- Receive training on how to inject SKYRIZI before giving an injection. Talk to your doctor, pharmacist or nurse if you need help.
- 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 expiration date has passed.**
- **Do not use if the liquid has been frozen (even if thawed).**
- **Do not shake the syringe.**
- **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.**

**Follow the steps below each time you use SKYRIZI.**

### STEP 1



**Place the following on a clean, flat surface:**

- 2 pre-filled syringes and 2 alcohol pads (provided).
- 2 cotton balls or gauze pads (not provided).
- Special disposal container (not provided).

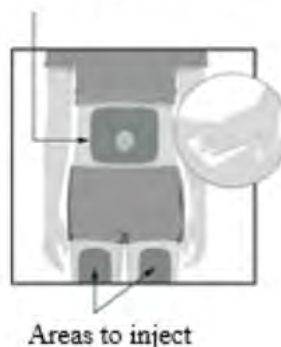
Wash and dry your hands.

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



Choose from these 3 areas to inject:

- Front of left thigh.
- Front of right thigh.

- Belly (abdomen) at least 5 cm from the belly button (navel).

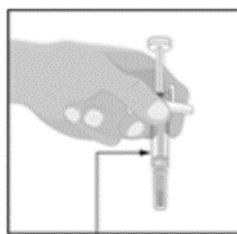
For the second syringe, inject at least 3 cm away from the first injection.

**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 touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting.**
- **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.**

**STEP 3**



Check liquid

Hold the syringe with covered needle pointing down, as shown.

Check the liquid in the syringe.

- 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.**

**STEP 4**



Removing the needle cover:

- Hold the syringe in one hand between the finger grip and needle cover.

- With the other hand, gently pull the needle cover straight off.
- **Do not hold or pull plunger rod when removing the needle cover.**
- 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.**

**STEP 5**

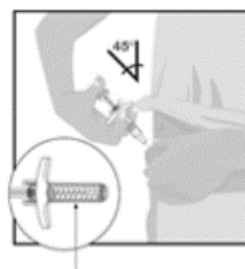


Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

Gently pinch the area of cleaned skin with your other hand and hold it firmly.

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.

**STEP 6**



Needle guard

Slowly push the plunger rod all the way in until all of the liquid is injected.

Pull the needle out of the skin while keeping the syringe at the same angle.

Stop pinching the skin around your injection site.

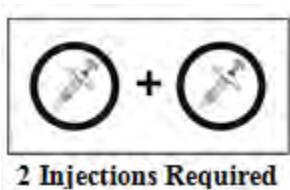
Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- The needle guard will not activate unless all the liquid is injected.
- Speak to your doctor, pharmacist or nurse if you think you may have not given a full dose.

Press a cotton ball or gauze pad where you have injected and hold for 10 seconds.

**Do not rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal.**

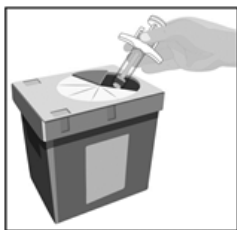
#### STEP 7



**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 straight after the first injection but at least 3 cm away from the first injection.

#### STEP 8



Throw away used syringes in a special disposal container right away after use.

- **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.

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