SKYRIZI®

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Skyrizi?

Skyrizi contains the active ingredient risankizumab. Skyrizi is used to treat adults with moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn's disease, and moderate to severe ulcerative colitis.

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?

Things you should do	• Ensure you are up to date with your immunisations before you start therapy with Skyrizi. • Speak to your doctor if you think you have an infection. • Remind any doctor or dentist you visit that you are using Skyrizi.
Things you should not do	• 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	• Store Skyrizi in the refrigerator at 2°C to 8°C. Do not freeze. • Keep it in the original carton until it's time to inject it to protect it from light.

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 possible serious allergic reaction (anaphylaxis), including difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, low blood pressure, which can cause dizziness, feeling faint or lightheadedness.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

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.

Psoriasis: Skyrizi reduces inflammation and can therefore help to improve skin clearance and the appearance of nails. It also reduces symptoms of plaque psoriasis such as burning, itching, pain, redness and scaling.

Psoriatic Arthritis: Skyrizi reduces the inflammation and can therefore help to reduce pain, stiffness and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, psoriatic nail damage and it may limit damage to the bone and cartilage in your joints. These effects can ease your normal daily activities, reduce tiredness and improve your quality of life.

Crohn's disease: Skyrizi reduces inflammation and can therefore help reduce signs and symptoms such as abdominal pain, diarrhoea and tiredness, as well as improve healing of the bowel, which can help improve your quality of life.

Ulcerative Colitis: Skyrizi reduces inflammation and can therefore help to reduce signs and symptoms of your disease such as abdominal pain, bloody stools, frequent and loose stools, and tiredness, as well as improve healing of the bowel, which can help improve your quality of life.

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 indicated for patients under the age of 18 years, therefore Skyrizi is not recommended for children.

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

Psoriasis/Psoriatic arthritis:

The dose is 150 mg. After the first dose, you will have the next dose 4 weeks later and then every 12 weeks. If using the 150 mg/mL pre-filled syringe or pre-filled pen, each dose is given as one 150 mg injection.

Crohn's disease and Ulcerative colitis:

You will begin treatment with Skyrizi with a starting dose (known as induction phase) which will be given by your doctor, nurse or healthcare professional through a drip in your arm (intravenous infusion).

Starting doses

	How much?	When?
Crohn's disease	600 mg	Week 0 (When your doctor tells you)
	600 mg	Week 4 (4 weeks after your first starting dose)
	600 mg	Week 8 (4 weeks after your second starting dose)
Ulcerative colitis	1200 mg	Week 0 (When your doctor tells you)
	1200 mg	Week 4 (4 weeks after your first starting dose)
	1200 mg	Week 8 (4 weeks after your second starting dose)

Afterwards, you will receive, or you will be able to inject SKYRIZI using a pre-filled cartridge with an on-body injector as an injection under your skin (subcutaneous injection).

Maintenance doses

	How much?		When?
Crohn's disease	First maintenance dose	360 mg	Week 12 (4 weeks after the last starting dose)
	Further doses	360 mg	Week 20 and every 8 weeks, starting after the first maintenance dose
Ulcerative colitis	First maintenance dose	180 mg or 360 mg	Week 12 (4 weeks after the last starting dose)
	Further doses	180 mg or 360 mg	Week 20 and every 8 weeks, starting after the first maintenance dose

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

How to inject Skyrizi

Skyrizi 150 mg/mL pre-filled syringe and pen, 180 mg/1.2 mL pre-filled cartridge with on-body injector and 360 mg/2.4 mL pre-filled cartridge with on-body injector are injected under your 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.

Skyrizi 600 mg/10 mL

- Skyrizi 600 mg/10 mL single-use vial for intravenous infusion will be given by your doctor, nurse or health care professional through a vein in your arm (intravenous infusion).
- Skyrizi 600 mg/ 10 mL should be prepared and given by a healthcare professional using aseptic technique.

Click on the link for the instructions on how to inject 150 mg/mL pre-filled syringe:
https://www.medsinfo.com.au/media/veis150s
Click on the link for the instructions on how to inject 150 mg/ mL pen:
https://www.medsinfo.com.au/media/veis150p
Click on the link for the instructions on how to inject using the 180 mg/1.2 mL pre-filled cartridge with on-body injector:
https://www.medsinfo.com.au/media/veipfcx2
Click on the link for the instructions on how to inject using the 360 mg/2.4 mL pre-filled cartridge with on body injector:
https://www.medsinfo.com.au/media/veipfcx2
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.

Blood tests to check your liver (Crohn's disease or ulcerative colitis)

- Blood tests will be taken before, during and up to 12 weeks treatment

Call your doctor straight away if you:

- 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 in the original carton to protect it from light.

If needed, you may also store Skyrizi 150 mg/mL pen or pre-filled syringe, Skyrizi 180 mg/1.2 mL or 360 mg/2.4 mL pre-filled cartridge with on-body injector one time out of the refrigerator (up to a maximum of 25°C) for up to 24 hours in the original carton to protect from light.

If unopened and stored below 25°C for less than 24 hours, you may return the Skyrizi 150 mg/mL pen or pre-filled syringe, or 180 mg/1.2 mL or 360 mg/2.4 mL prefilled cartridge with on-body injector to the refrigerator.

The pre-filled 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.

The pre-filled pen can be taken out of the fridge 30 to 90 minutes before injected, provided it is kept in the carton.

The pre-filled cartridge with on-body injector can be taken out of the fridge to reach room temperature for 45 to 90 minutes before injected, provided they are kept in the carton. Keep out of direct sunlight.

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, pen or on-body injector 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
Upper respiratory tract infection: • sore throat • stuffy nose **Skin:** • fungal skin infection, such as athlete's foot (tinea) • pain, or redness at the injection site • small raised red bumps on the skin **General:** • headache • feeling especially tired **Other side effects (Crohn's disease or ulcerative colitis)** **Muscle or bone:** • joint pain and/or swelling • back pain **Gut:** • pain in belly **Urinary tract infection:** • burning when passing urine and/or passing urine more often **General:** • fever	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• anaemia	

Serious side effects

Serious side effects	What to do
Signs of a serious allergic reaction (anaphylaxis): • difficulty breathing or swallowing • swelling of face, lips, tongue or throat • severe itching of skin, with a red rash or raised bumps • low blood pressure, which can cause dizziness, feeling faint or lightheadedness	**Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Signs of a serious infection: • fever • flu-like symptoms • night sweats • feeling tired or short of breath • cough that won't go away • warm, red painful skin • painful skin rash with small red blisters **Signs of liver problems (Crohn's disease or ulcerative colitis):** • yellowing of the skin and eyes • loss of appetite • vomiting • unexplained rash • nausea • stomach pain • tiredness • dark urine	**Call your doctor straight away, if you notice any of these serious side effects.**

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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

Active ingredient (main ingredient)	risankizumab
Other ingredients 150 mg/mL, 600 mg/10 mL, 180 mg/1.2 mL and 360 mg/2.4 mL (inactive ingredients)	• sodium acetate trihydrate • glacial acetic acid • trehalose dihydrate • polysorbate 20 • water for injections

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

Not all presentations may be marketed.

What Skyrizi looks like

Skyrizi 150 mg/mL liquid should look clear to yellow and may contain tiny white or clear particles. Do not inject if the liquid is cloudy or contains flakes or large particles. It is supplied in a 150 mg/mL pre-filled syringe with needle guard or a 150 mg/mL pre-filled pen. Each carton contains one pre-filled syringe (AUST R 342813) or one pre-filled pen (AUST R 342814).

Skyrizi 600 mg/10 mL liquid should look colourless to slightly yellow and may contain tiny white or clear particles. Do not inject if the liquid is cloudy or contains flakes or large particles. It is supplied as a concentrate solution for infusion in a single dose 600 mg/10 mL vial. Each carton contains one vial (AUST R 375984).

Skyrizi 180 mg/1.2 mL and 360 mg/2.4 mL liquid should look clear and colourless to yellow and may contain tiny white to clear particles. Do not inject if the liquid is cloudy or contains flakes or large particles. It is supplied in a 180 mg/1.2 mL pre-filled cartridge with on-body injector or a 360 mg/2.4 mL pre-filled cartridge with on-body injector. Each carton contains one pre-filled cartridge with on-body injector (360 mg/2.4 mL - AUST R 375976 or 180 mg/1.2 mL - AUST R 427219).

Who distributes Skyrizi?

SKYRIZI is distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

SKYRIZI is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria Street
Wellington 6011
New Zealand

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