

SKYRIZI SOLUTION FOR INJECTION IN PRE-FILLED PEN 150MG/ML

Risankizumab (150 mg/mL)

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What Skyrizi is used for

Skyrizi contains the active substance risankizumab.

Skyrizi is used to treat adults with moderate to severe plaque psoriasis, active psoriatic arthritis and moderate to severe palmoplantar pustulosis.

How Skyrizi works

This medicine works by stopping a protein in the body called 'IL-23', which causes inflammation.

Plaque 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.

Palmoplantar Pustulosis

SKYRIZI reduces inflammation and can therefore help to improve skin clearance on the palms and/or soles of the feet.

Before you use Skyrizi

- When you must not use it

- if you are allergic to risankizumab or any of the other ingredients of this medicine.
- if you have an infection, including active tuberculosis, which your doctor thinks is important.

Children and adolescents

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

Pregnancy and lactation

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 how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 21 weeks after your last dose of Skyrizi.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

- Before you start use it

Talk to your doctor, pharmacist or nurse before and during the use of Skyrizi:

- if you currently have an infection or if you have an infection that keeps coming back.
- if you have tuberculosis (TB).
- if you have recently received or plan to receive an immunisation (vaccine). You should not be given certain types of vaccines while using Skyrizi.

- Taking other medicines

Tell your doctor, pharmacist or nurse:

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. You should not

be given certain types of vaccines while using Skyrizi.

If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of Skyrizi.

How to use Skyrizi

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This medicine is given as an injection under your skin (called a 'subcutaneous injection').

How much to use

Each dose is 150 mg given as a single injection. After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

- When to use it

You and your doctor, pharmacist or nurse will decide if you should inject this medicine 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 they have been trained.

- How long to use it

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

- If you forget to use it

If you forget to use Skyrizi, inject a dose as soon as you remember. Talk to your doctor if you are not sure what to do.

- If you use too much (overdose)

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

While you are using it

- Things you must do

- If you are about to be started on any new medicine, remind your doctor

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and pharmacist that you are using Skyrizi.

- Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.
- If you become pregnant while using this medicine, tell your doctor immediately.

- Things you must not do

- You should not receive a live vaccine while taking Skyrizi. Talk to your doctor, pharmacist or nurse before receiving any vaccination while taking Skyrizi. Do not use Skyrizi to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine or lower the dosage without checking with your doctor.

- Things to be careful of Serious allergic reactions

Skyrizi can cause serious side effects, including serious allergic reactions ('anaphylaxis').

Tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction while you are taking Skyrizi such as:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or light headedness
- severe itching of the skin, with a red rash or raised bumps

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Allergic reactions – these may need urgent treatment. Tell your doctor or get

emergency medical help straight away if you notice any of the following signs:

Serious allergic reactions ('anaphylaxis') are rare in people taking Skyrizi (may affect up to 1 in 1 000 people). Signs include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or lightheadedness

Talk to your doctor or get medical help immediately if you have the following symptoms.

Symptoms of a serious infection such as:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using Skyrizi.

Other side effects

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 (such as redness or pain)
- itching
- headache
- rash
- eczema

Uncommon: may affect up to 1 in 100 people

- small raised red bumps on the skin
- hives (urticaria)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))

Storage and Disposal of Skyrizi

- Storage

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

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

If needed, you may also store SKYRIZI 150 mg/mL pen out of the refrigerator (up to a maximum of 25°C) for up to 24 hours in the original carton to protect from light.

Do not use this medicine if the liquid is cloudy or contains flakes or large particles.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

Skyrizi is a clear and colourless to yellow liquid in a pre-filled pen. The

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liquid may contain tiny white or clear particles.

Each pack contains 1 pre-filled pen.

- Ingredients

The active substance is risankizumab.

Each pre-filled pen contains 150 mg of risankizumab in 1 ml solution.

The other ingredients are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injection.

SKYRIZI 150 mg/mL contain less than 1 mmol sodium (23 mg) per 150 mg dose, i.e., essentially 'sodium-free'.

- MAL number:

MAL22086006ACRZ

Manufacturer

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

Product Registration Holder

AbbVie Sdn Bhd
Level 9 Menara Lien Hoe
No.8 Persiaran Tropicana
Tropicana Golf & Country Resort
47410 Petaling Jaya, Selangor Darul
Ehsan.
MALAYSIA

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