Package leaflet: Information for the patient

Skyrizi 600 mg concentrate for solution for infusion
risankizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Skyrizi is and what it is used for

Skyrizi contains the active substance risankizumab.

Skyrizi is used to treat patients 16 years and older with moderate to severe Crohn's disease and adult patients with moderate to severe ulcerative colitis.

How Skyrizi works

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

Crohn's disease
Crohn's disease is an inflammatory disease of the digestive tract. If you have active Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn's disease.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the large bowel. If you have active ulcerative colitis you will first be given other medicines. If these medicines do not work well enough or if you cannot take these medicines, you will be given Skyrizi to treat your ulcerative colitis.

Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

2. What you need to know before you are given Skyrizi

You should not be given Skyrizi
- if you are allergic to risankizumab or any of the other ingredients of this medicine (listed in section 6).

- if you have an infection, including active tuberculosis, which your doctor thinks is important.

Warnings and precautions
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.

It is important that your doctor or nurse keep a record of the batch number of your Skyrizi.
Every time you get a new pack of Skyrizi, your doctor or nurse must note down the date and the batch number (which is on the packaging after "Lot").

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

Children and adolescents
Skyrizi is not recommended for children and adolescents under 16 years of age. This is because Skyrizi has not been studied in this age group.

Other medicines and Skyrizi
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.

Pregnancy, contraception and breast-feeding
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.

Driving and using machines
Skyrizi is not likely to affect your driving and use of machines.

Skyrizi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How Skyrizi will be given

You will begin treatment with Skyrizi with a starting dose which will be given by your doctor or nurse through a drip in your arm (intravenous infusion).

Starting doses

	How much?	When?
Crohn's disease	600 mg	When your doctor tells you
	600 mg	4 weeks after 1st dose
	600 mg	4 weeks after 2nd dose

	How much?	When?
Ulcerative colitis	1 200 mg	When your doctor tells you
	1 200 mg	4 weeks after 1st dose
	1 200 mg	4 weeks after 2nd dose

Afterwards, you will receive Skyrizi as an injection under your skin. See package leaflet for Skyrizi 180 mg and 360 mg solution for injection in cartridge.

Maintenance doses

	How much?		When?
Crohn's disease	1st maintenance dose	360 mg	4 weeks after the last starting dose (at week 12)
	Further doses	360 mg	Every 8 weeks, starting after the 1st maintenance dose

	How much?		When?
Ulcerative colitis	1st maintenance dose	180 mg or 360 mg	4 weeks after the last starting dose (at week 12)
	Further doses	180 mg or 360 mg	Every 8 weeks, starting after the 1st maintenance dose

If you forget to use Skyrizi
If you forget or miss the appointment for any of your doses, contact your doctor to reschedule your appointment as soon as you remember.

If you stop using Skyrizi
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.

4. Possible 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 a 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 light-headedness

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)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Skyrizi

Skyrizi 600 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

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 vial label and outer carton after 'EXP'.

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

Keep the vial in the original carton in order to protect from light.

Do not shake the Skyrizi vial. Prolonged vigorous shaking can damage the medicine.

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

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Skyrizi contains

- The active substance is risankizumab. Each vial contains 600 mg of risankizumab in 10 mL solution (60 mg/mL).
- The other ingredients are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injections.

What Skyrizi looks like and contents of the pack

Skyrizi is a clear and colourless to slightly yellow liquid in a vial. The liquid may contain tiny white or clear particles.

Each pack contains 1 vial.

Marketing Authorisation Holder

AbbVie Ltd
Maidenhead
SL6 4UB
UK
Tel: +44 (0)1628 561090

Manufacturer

AbbVie S.r.l.
04011 Campoverde di Aprilia
(Latina)
Italy

or

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

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The following information is intended for healthcare professionals only

Traceability

In order to improve the traceability of biological medicinal products, the tradename and the batch

number of the administered product should be clearly recorded.

Instructions for intravenous induction dosing regimen

1. Skyrizi should be prepared by a healthcare professional using aseptic technique.

2. Skyrizi medicinal product must be diluted before administration.

3. Skyrizi for intravenous administration must be diluted into an intravenous infusion bag or glass bottle containing 5% dextrose in water (D5W) or sodium chloride 9 mg/mL (0.9%) solution for infusion to a final drug concentration of approximately 1.2 mg/mL to 6 mg/mL. Refer to table below for dilution instructions based on patient's indication.

Indication	**Intravenous induction dose**	**Number of 600 mg/ 10 mL vials**	**Total volume of 5% dextrose or sodium chloride 9 mg/mL (0.9%) solution for infusion**
Crohn's disease	600 mg	1	100 mL, or 250 mL, or 500 mL
Ulcerative colitis	1 200 mg	2	250 mL, or 500 mL

4. Prior to the start of the intravenous infusion, the content of the infusion bag or glass bottle should be at room temperature.
5. Infuse the diluted solution over a period of at least one hour for the 600 mg dose; at least two hours for the 1 200 mg dose.
6. Skyrizi vial solution should not be administered concomitantly in the same intravenous line with other medicinal products.

Each vial is for single use only and any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Handling and Storage of the vial and diluted solution:

- The solution in the vial and dilutions should not be shaken.
- The prepared infusion should be used immediately. If not used immediately, the diluted Skyrizi solution can be stored (protected from light) for up to 20 hours between 2°C to 8°C.
- Immediately after preparation or removal from refrigerator, the diluted Skyrizi solution can be stored at room temperature (protected from sunlight) for 8 hours. Storage time at room temperature begins once the diluted solution has been prepared. The infusion should be completed within 8 hours after dilution in the infusion bag.
- Exposure to indoor light is acceptable during room temperature storage and administration.
- Do not freeze.