EMA/804315/2022
EMEA/H/C/004759

Skyrizi (*risankizumab*)

An overview of Skyrizi and why it is authorised in the EU

What is Skyrizi and what is it used for?

Skyrizi is a medicine used to treat adults with:

- moderate-to-severe plaque psoriasis (a disease causing red, scaly patches on the skin) who require systemic treatment (treatment with medicines given by mouth or by injection);
- active psoriatic arthritis (a disease that causes psoriasis and inflammation of the joints) when treatment with one or more medicines known as disease-modifying anti-rheumatic drugs (DMARDs) has not worked well enough or causes unacceptable side effects;
- moderate-to-severe Crohn's disease (a disease causing inflammation of the digestive tract) when conventional or biological treatments do not work well enough or cause unacceptable side effects.

When used for psoriatic arthritis, Skyrizi can be given alone or with another medicine, methotrexate.

Skyrizi contains the active substance risankizumab.

How is Skyrizi used?

Skyrizi can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating plaque psoriasis, psoriatic arthritis or Crohn's disease.

For plaque psoriasis and psoriatic arthritis, Skyrizi is available in pre-filled syringes and pre-filled pens. It is injected under the skin in an area that is clear of psoriasis, usually on the thigh or belly. The first two doses are given 4 weeks apart, while subsequent doses are given every 12 weeks. The doctor may decide to stop treatment if the condition does not improve after 16 weeks.

Two formulations are used for Crohn's disease. The first, a concentrate, is used to make a solution which is given at the start of treatment as an infusion (drip into a vein) three times over eight weeks. The second formulation, a solution for injection in a cartridge, is for long-term maintenance treatment and is given as an injection under the skin 4 weeks after the last infusion and then every 8 weeks thereafter.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

After being trained, patients may inject Skyrizi themselves if the doctor considers it appropriate. For more information about using Skyrizi, including the recommended doses, see the package leaflet or contact your doctor or pharmacist.

How does Skyrizi work?

The active substance in Skyrizi, risankizumab, is a monoclonal antibody (a type of protein) that is designed to attach to interleukin-23 (IL-23) and block its activity. IL-23 is involved in causing inflammation that is linked to arthritis, plaque psoriasis and Crohn's disease. By blocking the action of IL-23, risankizumab reduces inflammation and other symptoms associated with these conditions.

What benefits of Skyrizi have been shown in studies?

Plaque psoriasis

In four main studies involving over 2,100 patients with moderate to severe plaque psoriasis who required systemic treatment, Skyrizi was more effective than placebo (a dummy treatment) and comparator medicines at improving symptoms.

In the first two studies in a total of 997 patients, after 16 weeks of treatment around 75% of patients receiving Skyrizi had a reduction of at least 90% in PASI scores (a measure of how severe and widespread the skin lesions are), compared with around 45% of those receiving ustekinumab and around 4% of those receiving placebo. In addition, around 86% of patients receiving Skyrizi had clear or almost clear skin, compared with around 62% of those receiving ustekinumab and around 6% of those receiving placebo. Improvements in symptoms were maintained after 52 weeks of treatment with Skyrizi.

In the third study involving 605 patients, after 16 weeks of treatment 72% of patients receiving Skyrizi had a reduction of at least 90% in PASI scores, compared with 47% of those receiving adalimumab. In addition, 84% of patients receiving Skyrizi had clear or almost clear skin, compared with 60% of those receiving adalimumab.

Finally, in the fourth study involving 507 patients, after 16 weeks of treatment 73% of patients receiving Skyrizi had a reduction of at least 90% in PASI scores, compared with 2% of those receiving placebo. Around 84% of patients receiving Skyrizi had clear or almost clear skin, compared with around 7% of those receiving placebo. In a second part of this study, some patients who first received Skyrizi were then switched to placebo after 28 weeks while others remained on Skyrizi. At week 52, more patients who remained on Skyrizi had clear or almost clear skin than those who were switched to placebo.

Psoriatic arthritis

Two main studies involving over 1,400 patients with psoriatic arthritis showed that Skyrizi is more effective than placebo at improving symptoms.

In both studies, patients received either Skyrizi or placebo and more than half of the patients were also taking methotrexate. The main measure of effectiveness was a reduction in symptoms of 20% or more based on a standard rating score (ACR20) after 24 weeks of treatment.

The first study involved 443 patients whose condition had not responded adequately to previous treatment with at least one DMARD or another type of medicine known as a biological medicine. After 24 weeks, symptoms had decreased by at least 20% in 51% of patients taking Skyrizi compared with 27% of those taking placebo.

The second study involved 964 patients whose psoriatic arthritis had not responded adequately to previous treatment with at least one DMARD. After 24 weeks, symptoms had decreased by at least 20% in 57% of patients taking Skyrizi compared with 34% of those taking placebo.

Crohn's disease

Two main studies involving 1,549 patients looked at how effective Skyrizi was at treating moderate-to-severe Crohn's disease when other treatments did not work well enough or caused unacceptable side effects.

In the first study, 35% of those who received the recommended dose of Skyrizi infusions over 8 weeks had a clinical remission (little or no symptoms of high stool frequency and abdominal pain) after 12 weeks while 29% of them had an endoscopic response (based on a reduction in inflammation in the intestines). The results for patients who received placebo were 19% and 11% respectively.

In the second study, 44% of those who received the recommended dose of Skyrizi infusions had a clinical remission after 12 weeks while 40% of them had an endoscopic response. The results for patients who received placebo in this study were 22% and 12% respectively.

A third study of 542 patients from the two main studies who responded to treatment looked at the effectiveness of maintenance treatment given under the skin every 8 weeks. After a year, around 52% of those receiving Skyrizi were in remission and 47% had an endoscopic response compared with 40% and 22% respectively of those receiving placebo.

What are the risks associated with Skyrizi?

The most common side effect with Skyrizi (which may affect more than 1 in 10 people) is upper respiratory infection (nose and throat infection).

Skyrizi must not be used in patients who have an ongoing infection that the doctor considers important.

For the full list of side effects and restrictions, see the package leaflet.

Why is Skyrizi authorised in the EU?

Studies have shown that Skyrizi is highly effective at clearing the skin in patients with plaque psoriasis and reduces symptoms of psoriatic arthritis; the positive effects are maintained with continued use. Skyrizi is also effective at treating symptoms of moderate to severe Crohn's disease and reducing signs of inflammation in the intestines. There are few side effects, the most important one being infection.

The European Medicines Agency therefore decided that Skyrizi's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Skyrizi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Skyrizi have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Skyrizi are continuously monitored. Side effects reported with Skyrizi are carefully evaluated and any necessary action taken to protect patients.

Other information about Skyrizi

Skyrizi received a marketing authorisation valid throughout the EU on 26 April 2019.

Further information on Skyrizi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Skyrizi

This overview was last updated in 11-2022.