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Opzelura (*ruxolitinib*)

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

What is Opzelura and what is it used for?

Opzelura is a medicine used for treating non-segmental vitiligo, a disease that causes patches of skin to lose colour on both sides of the body. In patients with vitiligo, the immune system (the body's natural defences) attacks melanocytes (the skin cells that make pigment), causing patches of pale pink or white skin (depigmentation). Opzelura is used in adults and adolescents from 12 years of age with non-segmental vitiligo that also affects the face.

Opzelura contains the active substance ruxolitinib.

How is Opzelura used?

Opzelura can only be obtained with a prescription and treatment should be started and supervised by a doctor with experience in the diagnosis and treatment of non-segmental vitiligo.

Opzelura is available as a cream to be applied on the depigmented skin twice a day. Opzelura should not be applied to more than 10% of the body at the same time.

Treatment may be needed for more than 6 months to obtain satisfactory repigmentation of the skin (return of skin colour). The doctor may stop treatment if there is no satisfactory improvement after one year of treatment.

For more information about using Opzelura, see the package leaflet or contact your doctor or pharmacist.

How does Opzelura work?

The active substance in Opzelura, ruxolitinib, works by blocking enzymes known as Janus kinase (JAK) 1 and 2, which are involved in the activity of a substance called interferon-gamma (IFN-gamma). In vitiligo, IFN-gamma is thought to play a role in the activity of the cells of the immune system that attack melanocytes. By blocking JAK1 and JAK2, ruxolitinib reduces the immune system's ability to destroy melanocytes, allowing them to produce pigment.

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What benefits of Opzelura have been shown in studies?

In 2 main studies, Opzelura was shown to improve repigmentation compared with placebo (dummy treatment).

The main measure of effectiveness was the proportion of patients who achieved an improvement of at least 75% in the pigmentation of their face as measured using a standard score for facial vitiligo (F-VASI75) after 6 months.

The 2 studies involved a total of 661 patients with non-segmental vitiligo. On average, around 31% of patients who received Opzelura achieved an improvement of at least 75% in the pigmentation of their face after 6 months of treatment, compared with around 10% of those who received placebo. Using a standard score for total body pigmentation (T-VASI50), the studies further showed that, after 6 months, total body pigmentation improved by at least 50% in 22% of patients who used Opzelura compared with 6% of those receiving placebo.

What are the risks associated with Opzelura?

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

The most common side effect with Opzelura (which may affect up to 1 in 10 people) is acne at the site where the medicine was applied.

Women who are pregnant or breastfeeding must not use Opzelura.

Why is Opzelura authorised in the EU?

Opzelura has been shown to have beneficial effects on the repigmentation of the skin in patients with non-segmental vitiligo. In terms of safety, the side effects of Opzelura are considered acceptable. While ruxolitinib medicines taken by mouth are associated with serious side effects, these effects are not expected to occur with Opzelura since it is used as a cream, provided that it is not used on more than 10% of the body in one application.

The European Medicines Agency therefore decided that Opzelura'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 Opzelura?

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

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

Other information about Opzelura

Opzelura received a marketing authorisation valid throughout the EU on 19 April 2023.

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

This overview was last updated in 04-2023.