EMA/355342/2024
EMEA/H/C/006109

Anzupgo (delgocitinib)

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

What is Anzupgo and what is it used for?

Anzupgo is used to treat moderate to severe chronic hand eczema (a long-term condition where the skin of the hands is itchy, red and dry) in adults who cannot use corticosteroids applied to the skin or in whom such corticosteroids do not work well enough.

Anzupgo contains the active substance delgocitinib.

How is Anzupgo used?

Anzupgo can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of chronic hand eczema.

Anzupgo is available as a cream, that is applied as a thin layer to affected skin of the hands and wrists twice a day. The cream should be applied at regular intervals and treatment should be continued until symptoms improve or disappear, after which it can be stopped. If symptoms recur, treatment can be re-started as needed. If no improvement is seen after 12 weeks of continuous treatment, treatment should be stopped.

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

How does Anzupgo work?

The active substance in Anzupgo, delgocitinib, works by blocking the action of enzymes (proteins) known as Janus kinases. These enzymes play an important role in the process of inflammation that occurs in chronic hand eczema. Delgocitinib helps reduce the inflammation and other symptoms of the condition.

What benefits of Anzupgo have been shown in studies?

Anzupgo was more effective than a placebo (dummy) cream at reducing the extent and severity of symptoms in two main studies involving 960 adults with moderate to severe chronic hand eczema. In both studies, the main measure of effectiveness was the proportion of patients who achieved a score of

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

0 (clear) or 1 (almost clear) on a 5-point scale for chronic hand eczema (the IGA-CHE scale), with an improvement of at least 2 points after 16 weeks of treatment.

The results showed that most, or all, of the chronic hand eczema had cleared up in around 20% of patients treated with Anzupgo in the first study compared with around 10% of patients using placebo. In the second study, these figures were around 29% for patients treated with Anzupgo and around 7% for patients using placebo.

What are the risks associated with Anzupgo?

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

The most common side effects with Anzupgo (which may affect 1 in 100 people) include application site reactions such as itching, redness, pain and a burning or prickling sensation.

Why is Anzupgo authorised in the EU?

Anzupgo reduces the extent and severity of chronic hand eczema in adults with moderate to severe disease who cannot use corticosteroids that are applied to the skin or in whom such corticosteroids do not work well enough. At the time of approval of Anzupgo, treatment options for these patients were very limited.

Regarding safety, Anzupgo's side effects are generally mild and manageable. The European Medicines Agency therefore decided that Anzupgo's benefits are greater than its risks and it can be authorised in the EU.

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

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

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

Other information about Anzupgo

Anzupgo received a marketing authorisation valid throughout the EU on 19 September 2024.

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

This overview was last updated in 09-2024.