swissmedic

Summary report on authorisation dated 23 May 2025

Anzupgo® (active substance: delgocitinib)

Authorisation in Switzerland: 13 November 2024

Cream for the treatment of moderate to severe chronic hand eczema in adults

About the medicinal product

Anzupgo contains the active substance delgocitinib. It is used for treating moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to treatment with potent or highly potent topical corticosteroids, or for whom such treatment is not recommended.

Avoiding contact with the triggers of hand eczema, skin protection and good basic skin care are important components of the therapy.

CHE is a long-term recurring skin disorder that affects the hands and persists for more than three months or recurs at least twice a year. The condition can significantly impair daily life and work activities, since it often involves severe symptoms such as skin redness, scaling, thickening of the skin and intense itching.

Mode of action

Delgocitinib, the active substance in Anzupgo, belongs to a group of medicines called "Janus kinase inhibitors". It helps improve the condition of the skin by blocking certain enzymes in the body that trigger inflammation.

This inhibition reduces the inflammation of the skin, thereby alleviating typical symptoms of hand eczema such as redness, swelling, scaling and itching.

Use

Anzupgo is a prescription-only medicine that is supplied as a cream with an active substance concentration of 20 mg delgocitinib per gram of cream.

The usual dosage is the twice-daily application, in the morning and evening, of a thin layer of cream to the affected areas of the skin on the hands and wrists until the skin is free, or almost free, of symptoms.

If symptoms recur, the twice-daily application of the cream can be resumed as needed. No more than one 60 g tube per month should be used.

Efficacy

The efficacy of Anzupgo was investigated in the pivotal studies DELTA 1 and DELTA 2 with 960 adult patients with moderate to severe chronic hand eczema.

The trial participants received either Anzupgo cream (delgocitinib 20 mg/g) or a placebo (dummy drug) twice daily for 16 weeks.

The results were assessed using the 5-point scale for chronic hand eczema (IGA-CHE scale). The primary endpoint of the studies was the achievement of a score of 0 (symptom-free) or 1 (almost symptom-free). The results showed that many more patients who were treated with Anzupgo achieved this improvement compared to the placebo groups. The percentages were 19.7% in the DELTA-1 study and 29.1% in the DELTA 2 study whereas only 9.9% and 6.9%, respectively, of patients in the placebo groups showed a corresponding improvement in the scores.

Precautions, undesirable effects, and risks

Anzupgo must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects were application site reactions, including pain, itching, redness and tingling.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Only limited treatment options are currently available for patients with moderate to severe chronic hand eczema (CHE) who respond inadequately to, or who are not eligible for, potent or very potent topical corticosteroids.

The studies described above have shown that Anzupgo alleviates the symptoms of CHE and improves the appearance of the skin in a significant proportion of patients.

Taking all the risks and precautions into account, and based on the available data, the benefits of Anzupgo outweigh the risks.

Swissmedic has therefore authorised Anzupgo for the treatment of moderate to severe chronic hand eczema in adults for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Anzupgo®

Information for patients (package leaflet): Information for patients Anzupgo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.