Prescribing Information for Anzupgo® ▼ (delgocitinib) 20mg/g cream

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Indication: Treatment of moderate to severe chronic hand eczema (CHE) in adults for whom topical corticosteroids are inadequate or inappropriate.
Active ingredient: Each gram of cream contains 20 mg of delgocitinib.
Dosage and administration:
Posology: A thin layer of Anzupgo should be applied twice daily to the affected skin of the hands and wrists until the skin is clear or almost clear. It is recommended to apply the cream at regular intervals, approximately 12 hours apart. In the event of recurrence of the signs and symptoms of CHE (flares), twice daily treatment of the affected areas should be re-initiated as needed. Treatment should be discontinued if no improvement is seen after 12 weeks of continuous treatment.
Missed dose: If an application is missed, the cream should be applied as soon as possible. Thereafter, applications should be resumed at the regular scheduled time.
Special populations: No dose adjustment is recommended for elderly patients. No studies with Anzupgo have been performed in patients with severe hepatic or renal impairment. However, dose adjustment is not recommended due to the minimal systemic exposure of topically applied delgocitinib. The safety and efficacy of Anzupgo in children and adolescents below 18 years of age has not been established.
Method of administration: cutaneous use. A thin layer of Anzupgo should be applied to clean and dry skin of the affected areas of the hands and wrists. Patients should avoid applying other topical products immediately before and after.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Precautions and warnings:
Non-melanoma skin cancer (NMSC), predominantly basal cell carcinoma, has been reported in patients treated with topical JAK inhibitors. Periodic skin examination of the application site is recommended for all patients, particularly those with risk factors for skin cancer. Benzyl alcohol may cause allergic reactions or mild local irritation. Butylhydroxyanisole (E 320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
Drug interactions:
No clinical interaction studies have been performed with topically or systemically administered delgocitinib. Given the limited metabolism of delgocitinib, application to a limited body surface area (hands and wrists), and minimal systemic exposure of topically applied delgocitinib, there is a low potential for interaction with systemic treatments. Delgocitinib has not been evaluated in combination with other topical medicinal products and co-application on the same skin area is not recommended.
Fertility, pregnancy and lactation: There are no or a limited amount of data from the use of delgocitinib in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Anzupgo during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to delgocitinib is negligible. Anzupgo can be used during breast-feeding and care should be taken to avoid direct contact with the nipple or surrounding area after applying the cream to the hands and/or wrists. As a precautionary measure, care should be taken to avoid direct skin contact when taking care of an infant immediately after applying Anzupgo to the hands and/or wrists. No human data on the effect of delgocitinib on fertility are available. Based on findings in female rats, oral administration of delgocitinib resulted in reduced fertility at exposures considered sufficiently in excess of the human exposure. Animal studies did not indicate effects with respect to fertility in males.
Side effects: *Common (≥ 1/100 to < 1/10)*: Application site reactions.
Precautions for storage: Do not freeze.
Legal category: POM.
Marketing authorisation number and holder: PLGB 05293/0191. LEO Pharma A/S, Ballerup, Denmark.
List price: 60g tube: £595
Last revised: March 2025
Reference number: MAT-78383

Further information can be found in the Summary of Product Characteristics or from: LEO Pharma, Building 5, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UD, UK. e-mail: medical-info.uk@leo-pharma.com

Reporting of Suspected Adverse Reactions: Adverse events should be reported.
Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Drug Safety at LEO Pharma by calling +44 (0)1844 347333 or e-mail: medical-info.uk@leo-pharma.com