Package leaflet: Information for the user

Anzupgo® 20 mg/g cream
delgocitinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Anzupgo® is and what it is used for

Anzupgo contains the active substance delgocitinib. It belongs to a group of medicines called Janus kinase inhibitors.

Anzupgo is used in adults to treat moderate to severe chronic hand eczema. It is used when corticosteroid skin creams do not work well enough or cannot be used.

Anzupgo targets different proteins (enzymes) in the body called Janus kinases. It works by blocking the activity of four specific Janus kinase enzymes, which helps reduce inflammation and immune responses that cause hand eczema. By suppressing these processes, Anzupgo can help to improve the condition of the skin and reduce itching and pain. This, in turn, can increase the ability to perform daily activities and can improve the quality of life.

2. What you need to know before you use Anzupgo®

Do not use Anzupgo
- if you are allergic to delgocitinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Anzupgo.
Do not 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.

Children and adolescents
Do not use this medicine in children and adolescents below the age of 18 years because it has not been studied in this age group.

Other medicines and Anzupgo
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Using Anzupgo at the same time as other medicines on the affected skin is not recommended, as it has not been studied.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

The effects of this medicine in pregnant women are not known; therefore, it is preferable to avoid the use of Anzupgo if you are pregnant or think you may be pregnant.

It is unknown whether delgocitinib passes into human breast milk, but only very small amounts of this medicine are absorbed into the body. No risk to the baby is therefore anticipated and Anzupgo can be used during breast-feeding.

However, if you are breast-feeding, you should take care that this medicine does not to come into contact with your nipple or any other area where your baby may ingest it during feeding.

If you are taking care of a baby, you should also take care to avoid hand contact with the baby's skin immediately after applying Anzupgo. This is a precaution to limit any unnecessary exposure of the baby to this medicine. In the event of accidental transfer of the cream to the baby's skin, the cream can be wiped off.

Driving and using machines
This medicine is not expected to have any effect on your ability to drive or to use machines.

Anzupgo contains benzyl alcohol, butylhydroxyanisole, and cetostearyl alcohol
This medicine contains 10 mg of benzyl alcohol (E 1519) in each gram. 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.

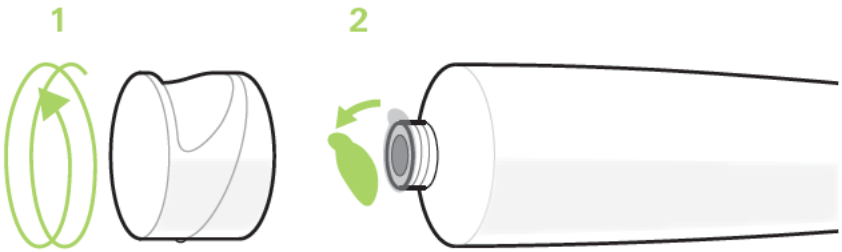
Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use Anzupgo®

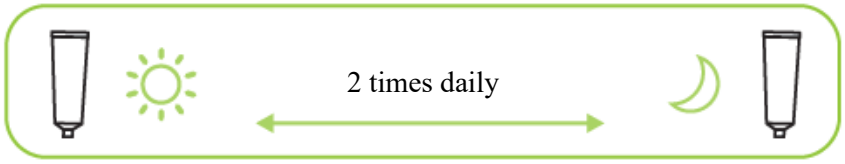
Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Anzupgo is for use on the skin only. Avoid contact with your eyes, mouth or nose. If the cream gets on any of these areas, thoroughly wipe off and/or rinse off the cream with water.

Before first use
1. Screw off the cap.
2. Peel off the seal at the top end of the tube. Screw the cap back on.



Dose and method of administration
- Avoid applying other products, such as creams or ointments, to the skin immediately before or after application of Anzupgo.
- Apply a thin layer of Anzupgo twice a day to the affected areas of your hands and wrists. Make sure your skin is clean and dry.



If someone else applies this medicine to your skin, they should wash their hands after application.

How long should you use Anzupgo
- You should use Anzupgo until your skin has become clear or almost clear, or as directed by your doctor.
- When instructed by your doctor, you can restart using Anzupgo if signs or symptoms of chronic hand eczema reappear.
- If you do not see any improvement after 12 weeks of treatment with Anzupgo, you should talk to your doctor.

If you use more Anzupgo than you should
If you have applied too much Anzupgo, wipe off the excess.

If you forget to use Anzupgo
If you forget to apply the cream at the scheduled time, do it as soon as you remember and then continue your normal schedule. Do not apply the cream more than twice a day.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with Anzupgo:

Common (may affect up to 1 in 10 people)
- Application site reactions (i.e., pain, itching, redness, and tingling)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card

Scheme,website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anzupgo®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not freeze.

The tube should be discarded 1 year after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Anzupgo contains
- The active substance is delgocitinib. Each gram of cream contains 20 mg of delgocitinib.
- The other ingredients are benzyl alcohol (E 1519), butylhydroxyanisole (E 320), cetostearyl alcohol, citric acid monohydrate (E 330), disodium edetate, hydrochloric acid (E 507) (for pH-adjustment), liquid paraffin, macrogol cetostearyl ether, and purified water (see section 2 "Anzupgo contains benzyl alcohol, butylhydroxyanisole, and cetostearyl alcohol").

What Anzupgo looks like and contents of the pack
Anzupgo is a white to slightly brown cream.

Anzupgo is supplied in tubes containing 15 or 60 grams of cream. There is one tube per carton. Not all pack sizes may be marketed.

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