

Package leaflet: Information for the patient

Staquis 20 mg/g ointment crisaborole

▼ 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 Staquis is and what it is used for
2. What you need to know before you use Staquis
3. How to use Staquis
4. Possible side effects
5. How to store Staquis
6. Contents of the pack and other information

1. What Staquis is and what it is used for

Staquis contains the active substance crisaborole. Staquis is used on the skin to control the symptoms of mild to moderate atopic dermatitis in adults and children from 2 years of age. Atopic dermatitis, also called atopic eczema, causes skin inflammation, redness, itchiness, dryness, and thickening in people prone to allergies. The ointment should not be used on more than 40% of your body surface area.

Crisaborole, the active substance in Staquis, is thought to work by reducing inflammation and some effects of the immune system (the body's defences).

2. What you need to know before you use Staquis

Do not use Staquis

- if you are allergic to crisaborole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Staquis.

Staquis is not for use in the eyes, mouth, or vagina; therefore, take care not to get this ointment into these areas. If the ointment accidentally gets into these areas, thoroughly wipe off and/or rinse off the ointment with water.

Stop using Staquis immediately and see your doctor if you get an allergic reaction. Symptoms include welts (hives), itching, swelling, and redness that are severe.

Skin reactions where this medicine is applied, such as burning or stinging, may be more likely to occur on sensitive skin areas such as the face and neck.

Children

Staquis has not been studied in children younger than 2 years of age; therefore, it should not be used in this group of children. Speak to your doctor, pharmacist, or nurse.

Other medicines and Staquis

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

Some medicines can affect the levels of Staquis in your body. You should inform your doctor if you are taking medicines containing the following active substances:

- ketoconazole, itraconazole (used to treat fungal infections)
- erythromycin, clarithromycin, ciprofloxacin (used to treat infections)
- ritonavir (used to treat HIV)
- fluvoxamine (used to treat depression).

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 or pharmacist for advice before using this medicine. The effects of this medicine in pregnant women are not known; therefore, do not use Staquis in pregnancy unless you have checked with your doctor that you can use it.

It is not known if Staquis passes into the milk after applying it to the skin. The effects of this medicine in breastfed infants are not known; therefore, Staquis should not be used if you are breast-feeding or are planning to breast-feed.

Driving and using machines

Staquis is unlikely to have an effect on your ability to drive and use machines.

Staquis contains propylene glycol

This medicine contains 90 mg propylene glycol in each gram of ointment.

3. How to use Staquis

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

Use in adults

- Apply a layer of the ointment twice daily to affected areas of your skin.
- This medicine can be used on all skin areas except on the scalp.
- The ointment should only be used on up to 40% of your body surface area.
- This medicine is for use on the skin only.

Wash your hands after applying this medicine, unless it is your hands that are being treated. If someone else applies this medicine to you, they should wash their hands after application.

This medicine can be used twice daily for up to 4 weeks per treatment course. As instructed by your doctor, you can use further treatment course(s) if your atopic dermatitis is not controlled or appears on new areas as long as you do not apply the ointment to more than 40% of your body surface area. If your atopic dermatitis is still there after 12 weeks of therapy, or if your atopic dermatitis gets worse, stop using the medicine and see your doctor.

Moisturisers (emollients) may be used on areas of the skin where Staquis is not applied. Do not use other topical medicines (such as ointments, creams, lotions) on areas of the skin where Staquis is applied without asking your doctor.

Use in children and adolescents

For children 2 years of age and older, and adolescents the instructions for use are the same as for adults.

If you use more Staquis than you should

If too much Staquis has been applied, the excess should be wiped off.

If you forget to use Staquis

If you forget to apply the ointment at the scheduled time, do it as soon as you remember and then continue your normal dosing schedule.

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.

Allergic reactions may occur uncommonly. Allergic reactions include severe symptoms of:

- hives
- itching
- swelling
- redness.

If you have an allergic reaction, stop using this medicine immediately and talk with your doctor or pharmacist.

Other side effects may include:

Common (may affect up to 1 in 10 people)

- Skin reactions where this medicine is applied such as pain (burning or stinging), itching, rash, redness, irritation, and hives.

The most common skin reaction, pain (burning or stinging), is usually mild to moderate and generally goes away after several applications.

Uncommon (may affect up to 1 in 100 people)

- Allergic reactions: includes severe symptoms of hives, itching, swelling, and redness.

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 national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Staquis

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 store above 25 °C. Do not freeze.

Once opened, use the tube within 1 year.

Keep the tube tightly closed.

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 Staquis contains

- The active substance is crisaborole.
One g of ointment contains 20 mg of crisaborole.
- The other ingredients are paraffin, white soft; propylene glycol (E 1520 [see section 2]); glycerol monostearate 40-55 (Type I); paraffin, hard; sodium calcium edetate.

What Staquis looks like and contents of the pack

Staquis is a white to off-white ointment. It is supplied in 2.5 g, 30 g, 60 g, and 100 g laminate tubes. There are six tubes per carton for the 2.5 g tubes. There is one tube per carton for the 30 g, 60 g, and 100 g tubes. Not all tube sizes may be marketed.

Each tube comes with a tube head with a peel seal, and a white cap closure.

Marketing Authorisation

Holder Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Medicinal product no longer authorised