PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

STAQUIS®

Crisaborole

Read all of this leaflet carefully before you start using STAQUIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- STAQUIS has been prescribed for you or your child personally and you should not share your or your child's medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is a medicine used on the skin to treat mild to moderate eczema (atopic dermatitis) in adults and children 3 months of age and older. STAQUIS should not be used for longer than 12 months of treatment.

2. What you need to know before you use STAQUIS

Do not use STAQUIS

- if you or your child are hypersensitive (allergic) to crisaborole or any of the other ingredients of STAQUIS (listed in section 6).

Warnings and precautions

Take special care with STAQUIS:

- if you or your child experience signs of an allergic reaction including hives, itching, swelling, and redness. Discontinue STAQUIS and contact a health care provider if you or your child experience any of these symptoms.

Children and adolescents

STAQUIS is not recommended for use in children below the age of 3 months.

Other medicines and STAQUIS

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

There are currently no known medicines that interact with STAQUIS.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

It is not known if STAQUIS may harm your unborn baby or if it passes into breast milk.

Driving and using machines

STAQUIS has no known influence on the ability to drive or use machines.

It is not always possible to predict to what extent STAQUIS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STAQUIS affects them.

3. How to use STAQUIS

Do not share medicines prescribed for you or your child with any other person.

Apply a thin layer of STAQUIS ointment twice daily to affected areas of the skin.

STAQUIS is for topical use only. Do not use STAQUIS in your or your child's mouth, eyes, nose, or vagina.

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

Your doctor will tell you how long your or your child's treatment with STAQUIS will last. Do not stop treatment early.

If you have the impression that the effect of STAQUIS is too strong or too weak, tell your doctor or pharmacist.

If you use more STAQUIS than you should

Because STAQUIS is for topical use only, it is unlikely that you or your child will overdose on STAQUIS. If you or your child applies too much STAQUIS, thoroughly wipe it off.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

In cases of accidental eye, nose, mouth or vaginal exposure, the ointment should be thoroughly washed off and the area cleansed with water.

If you forget to use STAQUIS

If you or your child forget to use STAQUIS, apply it as soon you remember then go back to the regular dosing schedule. Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects

STAQUIS can have side effects.

Not all side effects reported for STAQUIS are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while using STAQUIS, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- pain such as burning or stinging on the area where you applied STAQUIS.

Less frequent side effects

- red itchy rash
- itching
- worsening of eczema

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of STAQUIS.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com

5. How to store STAQUIS

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not use after the expiry date stated on the tube and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STAQUIS contains

- The active substance is crisaborole. Each gram of STAQUIS contains 20 mg of crisaborole (2 % w/w).
- The other ingredients are butylated hydroxytoluene, edetate calcium disodium, mono- and di-glycerides, paraffin, white petrolatum and propylene glycol.

What STAQUIS looks like and contents of the pack

White to off-white ointment.

STAQUIS is supplied in 30 g and 60 g multi-laminate tubes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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