

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

STAQUIS™

crisaborole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about STAQUIS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking STAQUIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What STAQUIS is used for

STAQUIS contains the active substance crisaborole. It is an ointment used on the skin (topical) to treat mild to moderate eczema (atopic dermatitis) in adults and children 2 years of age and older.

Do not use STAQUIS for a condition for which it was not prescribed.

STAQUIS is not currently recommended for use in children under 2 years of age as it has not been tested in children under 2 years.

This medicine belongs to a group of medicines called phosphodiesterase-4 inhibitors.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use STAQUIS

When you must not use it

Do not use STAQUIS if you have an allergy to:

- Crisaborole or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you use STAQUIS after the expiry date has passed, it may have no effect at all, or worse, have an entirely unexpected effect. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any of the following:

- other medicines
- foods
- preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known if STAQUIS will harm your unborn baby.

Tell your doctor if you are breast-feeding.

It is not known whether STAQUIS passes through breast milk. Therefore, if you are breast-feeding, you should discuss with your doctor whether to stop breast-feeding or stop using STAQUIS.

You have or have had any other medical conditions:

If you have not told your doctor about any of the above, tell them before you start using STAQUIS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and STAQUIS may interfere with each other.

Do not use STAQUIS together with other eczema (atopic dermatitis) medicines.

Emollients, used to moisturise and soothe dry skin, may be used on other areas of skin whilst using STAQUIS. Talk to your doctor about how to use emollients whilst taking STAQUIS.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use STAQUIS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to use

Apply a thin layer of STAQUIS to the affected areas twice a day, for example, once in the morning and once in the evening.

How to use it

STAQUIS is for use on skin (topical use) only. Do not use STAQUIS in your eyes, mouth, or vagina. STAQUIS, due

to its thick formulation, may not be ideal for use on the scalp (with hair).

Squeeze out enough STAQUIS from the tube to cover the affected areas with a layer of the ointment.

Rub the ointment into skin thoroughly.

Apply only in one direction on hairy skin to avoid causing skin irritation or inflammation.

If someone else applies STAQUIS for you, they should wash their hands after applying STAQUIS.

Do not swim, bathe, shower or wash off STAQUIS for at least 4 hours after dosing. If you do swim, bathe or shower within the 4 hour time period after dosing, DO NOT reapply any until your next scheduled dosing time.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it.

If you forget to use it

If you miss a dose, apply STAQUIS when you remember, if it is at least 8 hours before the next scheduled dosing. Otherwise, skip the missed dose and apply the next dose at the normally scheduled time.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

If you accidentally apply more Staquis to your skin than you were told to, wipe off the excess. It will not harm you.

If you or anyone else swallows some of the ointment, immediately telephone your doctor or Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital, even if there are no signs of discomfort or poisoning.

While you are using STAQUIS

Things you must do

Tell your doctor if STAQUIS is not making your condition better or if you are worried about any side effects.

Staquis may cause mild stinging when first applied to your skin. It is safe to continue use if you experience mild stinging with the first few applications. These symptoms are usually mild and normally subside after a few days of use.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking STAQUIS.

Things you must not do

Do not use STAQUIS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

It may harm them.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using STAQUIS.

This medicine helps most people with atopic dermatitis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The most common side effect of STAQUIS is application site pain, such as burning or stinging. Other side effects not listed here may also occur in some patients.

STAQUIS may cause allergic reactions at or near the application site. These can be serious. If you have any of

these symptoms below, stop using STAQUIS and tell your doctor immediately:

- Signs of an allergic reaction such as swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Hives or itching
- Redness or swelling at the application site.

These may be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

After using STAQUIS

Storage

Keep your ointment in the tube until it is time to use it.

If you take the ointment out of the tube, it might not keep well.

Keep STAQUIS in a cool dry place where the temperature stays below 25°C.

Do not store STAQUIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

STAQUIS is a white to off-white ointment in a tube.

Ingredients

STAQUIS contains 2% crisaborole (w/w) as the active ingredient.

STAQUIS also contains the following excipients:

- white soft paraffin
- propylene glycol
- glyceryl monostearate
- synthetic paraffin
- butylated hydroxytoluene
- sodium calcium edetate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

STAQUIS is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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