

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Staquis?

Staquis contains the active ingredient crisaborole. Staquis 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. This medicine belongs to a group of medicines called phosphodiesterase-4 inhibitors.

For more information, see Section [1. Why am I using Staquis?](#) in the full CMI.

2. What should I know before I use Staquis?

Do not use if you have ever had an allergic reaction to crisaborole or any of the ingredients listed at the end of the CMI under Section 7.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Staquis?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Staquis and affect how it works. Do not use Staquis together with other eczema (atopic dermatitis) medicines.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Staquis?

- Staquis is for use on skin (topical use) only.
- Apply a thin layer of Staquis to the affected areas twice a day, for example, once in the morning and once in the evening. Follow the instructions provided and use Staquis until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Staquis?](#) in the full CMI.

5. What should I know while using Staquis?

Things you should do	<ul style="list-style-type: none">• 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 using Staquis.
Things you should not do	<ul style="list-style-type: none">• 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.• Do not use this medicine after the expiry date.
Looking after your medicine	<ul style="list-style-type: none">• Keep your ointment in the tube until it is time to use it.• Keep Staquis in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Staquis?](#) in the full CMI.

6. Are there any side effects?

The most common side effect of Staquis is application site pain, such as burning or stinging. Staquis may cause allergic reactions at or near the application site, hives or itching, redness or swelling at the application site. If you have any of these symptoms, stop using Staquis and tell your doctor immediately. You may need urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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®

Active ingredient: *crisaborole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Staquis. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Staquis.**

Where to find information in this leaflet:

- [1. Why am I using Staquis?](#)
- [2. What should I know before I use Staquis?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Staquis?](#)
- [5. What should I know while using Staquis?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Staquis?

Staquis contains the active ingredient crisaborole.

Staquis 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.

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.

2. What should I know before I use Staquis?

Warnings

Do not use Staquis:

- if you are allergic to crisaborole, or any of the ingredients listed at the end of this leaflet under Section 7. 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.
- for a condition for which it was not prescribed.
- after the expiry date printed on the pack, or if the packaging is torn or show 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Staquis and affect how it works.

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 using Staquis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Staquis.

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

4. How do I use Staquis?

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.
- Follow the instructions provided and use Staquis until your doctor tells you to stop.

How long to use it

- Continue using this medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it.

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. DO NOT reapply any until your next scheduled dosing time.

If you forget to use Staquis

- 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 unsure what to do, ask your doctor or pharmacist.

If you use too much Staquis

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, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Staquis?

Things you should do

- 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.
- 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 using Staquis.

Things you should 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.

Driving or using machines

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

Looking after your medicine

- 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, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

Do not use this medicine after the expiry date.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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 list of side effects. You may not experience any of them.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • application site pain, such as burning or stinging 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">allergic reaction at or near the application site<ul style="list-style-type: none">signs of an allergic reaction such as swelling of the face, lips or tongue which may cause difficulty in swallowing or breathinghives or itchingredness or swelling at the application site	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>If you have any of these symptoms, stop using Staquis.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Do not be alarmed by this list of side effects. You may not experience any of them. Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

This medicine is not addictive.

What Staquis contains

Active ingredient (main ingredient)	crisaborole 2% (w/w)
Other ingredients (inactive ingredients)	white soft paraffin propylene glycol glyceryl monostearate synthetic paraffin butylated hydroxytoluene sodium calcium edetate

Do not take this medicine if you are allergic to any of these ingredients.

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

What Staquis looks like

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

AUST R 295283.

Staquis is available in a 60g tube.

Who distributes Staquis

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in September 2023.