

STAQUIS[®] TOPICAL OINTMENT 2%

Crisaborole (20 mg/gm)

What is in this leaflet

1. What Staquis Topical Ointment 2% is used for
2. How Staquis Topical Ointment 2% works
3. Before you use Staquis Topical Ointment 2%
4. How to use Staquis Topical Ointment 2%
5. While you are using it
6. Side effects
7. Storage and Disposal of Staquis Topical Ointment 2%
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Staquis Topical Ointment 2% is used for

Staquis Topical Ointment 2% is used on the skin to control the symptoms of mild to moderate atopic dermatitis in adults and children from 3 months of age and older.

How Staquis Topical Ointment 2% works

Staquis Topical Ointment 2% contains the active substance crisaborole. Crisaborole is thought to work by reducing inflammation and some effects of the immune system.

Before you use Staquis Topical Ointment 2%

- When you must not use it

Do not use Staquis Topical Ointment 2%:

-If you are allergic to crisaborole or any of the other ingredients of this medicine.

Pregnancy and lactation

The effects of this medicine in pregnant women are not known; therefore, do not use Staquis Topical Ointment 2% in pregnancy unless you have checked with your doctor that you can use it.

It is not known if Staquis Topical Ointment 2% passes into the milk after applying it to the skin. The effects of this medicine in breastfed infants are not known; therefore, Staquis Topical Ointment 2% should not be used without checking with your doctor, if you are breast-feeding or are planning to breast-feed.

To avoid unintentional ingestion by the newborn, STAQUIS Topical Ointment 2% should not be applied to the breast.

- Before you start to use it

Talk to your doctor or pharmacist before using Staquis Topical Ointment 2%.

Staquis Topical Ointment 2% is not for use in the eyes, mouth, or vagina; therefore, take care not to get this ointment into these areas.

In cases of accidental applying to these areas, the ointment should be thoroughly wiped off and/or rinsed with water.

Stop using Staquis Topical Ointment 2% and seek medical attention immediately if you get any allergic reaction after using it. Symptoms include itching, swelling, and redness that are severe.

- Taking other medicines

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

How to use Staquis Topical Ointment 2%

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

Apply a thin layer of Staquis Topical Ointment 2% twice daily to affected areas..

For maintenance, once affected areas are clear or almost clear, a layer of ointment is to be applied once daily to the most commonly affected areas. If signs and symptoms of the disease worsen, a layer of ointment is to be applied twice daily to affected areas.

- When to use it

Use as directed by your doctor or pharmacist.

Wash your hands after applying this medicine, unless it is your hands that are being treated. If someone else applies STAQUIS Topical Ointment 2% to you, they too should wash their hands after application.

- How long to use it

Continue taking Staquis Topical Ointment 2% for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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 use too much (overdose)

If too much Staquis Topical Ointment 2% has been applied, the excess should be wiped off.

While you are using it

- Things you must do

STAQUIS® TOPICAL OINTMENT 2%

Crisaborole (20 mg/gm)

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Staquis Topical Ointment 2%.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Staquis Topical Ointment 2% to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Staquis Topical Ointment 2% is unlikely to have an effect on your ability to drive and use machines.

Side effects

Like all medicines, Staquis Topical Ointment 2% can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Skin reactions where this medicine is applied such as pain (burning or stinging)

- - Allergic skin reactions with symptoms such as itching, swelling, and redness.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumer→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Staquis Topical Ointment 2%

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Keep tube tightly closed.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Staquis Topical Ointment 2% is a white to off-white ointment containing 2% crisaborole and is supplied in 2.5g, 30g and 60g laminate tubes.

- Ingredients

- Active ingredient
Crisaborole

- Inactive ingredients
White Petrolatum, Propylene Glycol, Mono- And Di-Glycerides, Paraffin, Butylated Hydroxytoluene, and Edetate Calcium Disodium.

- MAL number:

MAL24036010AZ

Manufacturer

Pharmacia and Upjohn Company LLC
7000 Portage Road
Kalamazoo
Michigan (MI) 49001
United States (USA)

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.,
Level 10 & 11, Wisma Averis,
Tower 2, Avenue 5, Bangsar South,
No. 8 Jalan, Kerinchi, 59200
Kuala Lumpur, Malaysia.

Date of Revision

16/12/2024

Serial Number

NPRA (R1/1) 28112024/224

PLD-STAQUIS -1224