

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Staquis<sup>®</sup>**

**Crisaborole 2% ointment.**

Each gram contains 20 mg crisaborole.

For a list of inactive ingredients and allergens in this preparation: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. WHAT IS THIS MEDICINE INTENDED FOR?**

Staquis is intended for topical treatment of mild to moderate atopic dermatitis (skin asthma) in adults and children 3 months of age and older.

**Therapeutic group:** phosphodiesterase 4 (PDE-4) inhibitor.

**2. BEFORE USING THIS MEDICINE**

**Do not use the medicine if:**

- |   |
|---|
| <ul style="list-style-type: none"><li>You are sensitive (allergic) to crisaborole or to any of the additional ingredients in this medicine (detailed in section 6).</li></ul> |
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**Special warnings regarding use of the medicine**

A hypersensitivity reaction (allergic reaction), including contact urticaria, can appear during the treatment with Staquis. Cases of severe itching, swelling and redness at the application site or at a distant site can be an indication of a hypersensitivity reaction (allergic reaction). If signs and symptoms of a hypersensitivity reaction (allergic reaction) appear, discontinue use immediately and seek medical assistance.

**Other medicines and Staquis**

**If you are taking, or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

**Pregnancy and breastfeeding**

Consult your doctor before using this medicine if:

- You are pregnant, may be pregnant, or are planning to become pregnant. There is not enough data to determine whether the use of Staquis may harm the unborn baby.
- You are breastfeeding, or planning to breastfeed. It is not known whether Staquis passes into breast milk.

### **Children and adolescents**

Staquis is intended for use in children from 3 months of age and above. The safety and efficacy of Staquis in children under 3 months of age are unknown.

### **Important information about some of the medicine's ingredients**

The preparation contains propylene glycol, which can cause skin irritation.

The preparation contains butylated hydroxytoluene, which can cause a localized skin reaction (e.g., contact dermatitis) or irritation of the eyes and mucous membranes.

## **3. HOW TO USE THIS MEDICINE?**

Always use this preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

The standard recommended method of use is application of a thin layer of Staquis to the affected areas, twice daily.

Wash your hands after applying Staquis, unless hands are being treated. If someone else applies Staquis for you, they should wash their hands after applying Staquis.

**Do not exceed the recommended dose.**

**Do not swallow.**

**Staquis is intended for external use on the skin only. This medicine is not intended for ophthalmic, oral or vaginal use.**

### **If you have accidentally taken a higher dosage**

If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

### **If you forget to take the medicine**

If you forgot to take the medicine according to the instructions for use, apply the medicine when you remember. Then, continue with the regular dosage. Do not apply a double dose the next time you use the medicine.

Persist with the treatment regimen as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, use of Staquis may cause side effects in some users. Do not be alarmed by the list of side effects; You may not experience any of them.

**Allergic reactions.** Staquis may cause allergic reactions at or near the application site. These reactions may be serious and may include hives, itching, swelling, and redness. If you experience any of these symptoms, stop using Staquis and seek medical assistance immediately.

The most common side effect ( $\geq 1\%$ ) of Staquis is pain at the application site, such as a burning or stinging sensation. Contact urticaria is a side effect occurring at a frequency of  $< 1\%$ .

**Side effects reported after the product has been marketed (frequency cannot be estimated reliably because reports are provided voluntarily by patients who used the product and there is no way to estimate the size of the population involved):** allergic contact dermatitis.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

## **5. HOW TO STORE THE MEDICINE?**

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Keep the tube tightly closed.

## **6. FURTHER INFORMATION**

**In addition to the active ingredient, this medicine also contains:**

White petrolatum, propylene glycol, mono- and di-glycerides, paraffin, butylated hydroxytoluene, and edetate calcium disodium.

**What the medicine looks like and what is the content of the pack:**

Staquis is a white to off-white ointment containing 2% crisaborole and is marketed in tubes of 2.5 grams, 30 grams and 60 grams.

Not all pack sizes may be marketed.

**Registration holder's and address:** Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

**Registration number of the medicine in the Ministry of Health's National Drug Registry:** 161-76-35303

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