PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is to be dispensed without a doctor's prescription

ORACORT E

Oral paste

Active ingredients - 1 gram of the preparation contains:

Triamcinolone acetonide 1 mg

Lidocaine hydrochloride monohydrate 30 mg

Inactive ingredients and allergens: see section 6 - "ADDITIONAL INFORMATION".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is not usually recommended for infants and children under two years of age. Under this age, contact a doctor.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult a pharmacist if you need further information. Contact a doctor if the signs of your illness (symptoms) get worse or do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Oracort E is indicated as an adjunctive treatment and for the temporary relief of symptoms and pain associated with oral inflammatory and ulcerative lesions.

Therapeutic Group:

Triamcinolone acetonide: synthetic corticosteroid for local treatment, with anti-inflammatory, antipruritic, and vasoconstrictive properties.

Lidocaine: local anesthetic.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients this medicine contains (see section 6).
- You are sensitive (allergic) to other amino amide local anesthetics.
- There exists a viral (such as herpes), fungal and/or bacterial infection of the mouth and/or throat or tuberculosis of the skin, especially during prolonged use of the preparation.

Special warnings about using the medicine

- Do not use this medicine frequently, or for a long period, without consulting the doctor.
- Special caution is required when using in children. Use in children requires medical supervision.
- If you are sensitive to any food or medication, inform the doctor before taking the medicine.
- If local irritation develops, stop treatment and refer to the doctor immediately.
- Special caution is required when using in patients with severe disorders of the heart pacemaker and conduction system, acute decompensated heart failure, and severe kidney and liver disorders. Although absorption of the paste into the body is low, general effects cannot be fully ruled out if the lining of the mouth is severely damaged.

Before treatment with Oracort E, tell the doctor if:

- You suffer, or have suffered in the past, from impaired function of the immune system.
- You suffer, or have suffered in the past, from diabetes mellitus.

Tests and follow-up:

A diagnostic test to detect allergic contact sensitization to corticosteroids should be carried out.

During the period of treatment you may also be referred for the following tests:

- Presence of cortisol in the urine.
- ACTH hormone stimulation.
- Adrenal activity test.
- General eosinophil count.
- Tests for glucose concentration in blood and urine.

These tests can help to evaluate whether damage has been caused in the activity of the hypothalamic-

pituitary-adrenal (HPA) axis.
Absorption into the body (systemic absorption) of topical corticosteroids has produced reversible suppression of hypothalamic-pituitary-adrenal (HPA) axis activity. Therefore, in patients receiving prolonged therapy with ointments containing corticosteroids, it is desirable to carry out periodic tests to evaluate suppression of HPA axis activity. If suppression of HPA axis activity is detected, an attempt should be made to withdraw the medicine or to reduce the frequency of use. Recovery of HPA axis function is generally immediate and complete upon discontinuation of therapy.

Drug interactions

If you are taking, or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell the doctor or pharmacist.
Clinically relevant interactions are very unlikely given the topical use and the amount used. However, the analgesic effect of other local anesthetics could potentially be increased.
The interactions with other medicines (antiarrhythmics, beta blockers) that are otherwise known to occur with lidocaine are unimportant with local administration of lidocaine on the lining of the mouth.

Using the medicine and food
Use the medicine after meals.

Pregnancy and breastfeeding
Do not use the medicine without consulting the doctor before starting treatment if you are pregnant, plan to become pregnant or if you are breastfeeding.

Children
The safety and efficacy of using Oracort E when treating children is unknown. Children may demonstrate greater susceptibility than adults when using topical corticosteroid preparations. Therefore, use should be limited to the least amount necessary. Chronic corticosteroid therapy may interfere with the growth and development of children.

3. HOW TO USE THIS MEDICINE?

Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
The recommended dose is usually:
2-3 times a day after meals and before bedtime.
Dosage for children: according to doctor's instructions.
Do not use the preparation in infants and children under 4 years of age for more than 3 weeks.
Discontinue use of the preparation after healing is achieved. If there is no improvement in your condition within 7 days, contact the doctor.
Do not exceed the recommended dose.

Directions for use:

Take a small quantity using a cotton swab and apply it by gentle pressure to cover the wound.
A larger quantity may be required for coverage of larger lesions. For optimal results use only the amount needed to coat the lesion with a thin film.
Do not rub in. Attempting to spread this preparation may result in a granular, stiffness sensation and cause the preparation to break apart and crumble. In any event, after application, a smooth, slippery film develops.
The preparation should be applied at bedtime to permit steroid contact with the lesion throughout the night.
Do not swallow! This medicine is intended for use in the oral cavity only.
Avoid contact with the eyes. If contact does occur, wash them immediately!

If you take an overdose, or if a child accidentally swallows some medicine, go immediately to a hospital emergency room and bring the medicine's package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the doctor.
Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

Like all medicines, taking Oracort E may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Stop treatment and contact the doctor as soon as possible if:

- You develop irritation, including irritation of the skin around the mouth (rare).
- You develop allergic reactions; in severe cases there may be acute hypersensitivity and even anaphylactic shock (very rare).
- Changes are detected in laboratory test results, see section “Tests and follow-up”.

Additional side effects

Rash, itching - these side effects usually disappear within a short time following the period of adaptation to the preparation.

Burning, dryness, blisters or peeling that did not exist prior to the treatment, skin inflammation around the mouth (perioral dermatitis), allergic contact dermatitis, softening and whitening (maceration) of the oral mucosa, secondary inflammations and atrophy of the oral mucosa, swelling, redness, hives, pain, changes in taste, numbness.

Side effects that may occur after prolonged use with corticosteroids for local treatment:

Cushing’s syndrome, increased levels of blood sugar (hyperglycemia), passing glucose in urine (glucosuria). These effects occur as a result of suppression of HPA axis activity (see “Tests and follow-up”).

Side effects and drug interactions in children and infants:

Parents must inform their doctor about any side effects and any additional medicines being taken by the child!

If you experience any side effect, if any side effect gets worse, or if you suffer from a side effect not mentioned in the 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) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the outer package and the tube. The expiry date refers to the last day of that month.

Store at a temperature below 25°C in a cool and dark place.

The shelf life after opening the preparation: 3 months.

Store in the original package.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

paraffin liquid, gelatin, pectin, carboxymethylcellulose sodium, polyethylene.

What the medicine looks like and the contents of the pack:

A thick yellow paste, with a granular appearance.

The medicine is marketed in tubes that contain 5 grams.

Manufacturer's and registration holder's name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor Street, Haifa Bay, 2624761.

Revised in August 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 037.10.22812