**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 in this medicine: 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.
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 corticosteroids 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 is a viral, fungal, and/or bacterial infection in your mouth and/or throat.

**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 local irritation develops, stop treatment and refer to the doctor immediately.
- A swallowing problem is possible, which could increase the chance of food, saliva, or stomach acids entering the airways (aspiration).
- Loss of feeling in your tongue, lips, or mouth may increase the risk of biting your tongue or the inside of your cheek.
- Patients with severe disorders in the heart's conduction system, acute heart failure, or severe kidney or liver disorders should avoid using the paste over a large area because increased blood flow increases the risk of effects over the whole body and of side effects.
- Use with caution if you have sores or a damaged lining of the mouth near the area to be treated. Destruction of the lining of the mouth increases systemic absorption, resulting in an increased risk of effects over the whole body and of side effects.

**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.

**Children and adolescents**
This medicine is not usually recommended for infants and children under two years of age. Under this age, contact a doctor.
The safety and efficacy of using Oracort E in children are unknown. Children may demonstrate greater

susceptibility than adults when using topical corticosteroid medicines. Therefore, use should be limited to the least amount necessary. Chronic corticosteroid therapy may interfere with the growth and development of children.

**Tests and follow-up**
If you do not respond to treatment, you may be referred for a diagnostic test to detect allergic contact sensitization to corticosteroids.
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.**
**Interactions with other medicines are very unlikely due to the type of use and the amount to be used. However, the effect of other local anesthetics might increase.**
**The known interactions of lidocaine with other medicines (medicines for heart rate, beta blockers) are not significant when lidocaine is administered locally on the lining of the mouth.**

**Using the medicine and food**
Use the medicine after eating or drinking, not before, to avoid swallowing the paste.

**Pregnancy and breastfeeding**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Lidocaine crosses the placenta and can reach your unborn baby. It is unknown whether triamcinolone acetonide crosses the placenta and can reach your unborn baby. A retrospective study of children born to mothers who used a medicine belonging to the same therapeutic class as triamcinolone acetonide while pregnant, found a 3-fold increase in frequency of harelip.
Lidocaine passes into breastmilk in small amounts. It is unknown whether triamcinolone acetonide passes into breastmilk when it is used inside the mouth.

Do not use this medicine if you are pregnant or breastfeeding unless your doctor considers it to be clearly necessary.

**Driving and using machines**

Taking this medicine is not expected to affect your ability to drive and use machines.

## 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 longer 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 sore.

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 <u>every time</u> 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. <u>SIDE EFFECTS</u>

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 allergic reactions. In the most serious cases an acute hypersensitivity reaction, and even anaphylactic shock (very rarely), are possible. If you get an allergic reaction, stop using this medicine and consult a doctor immediately.
- You develop irritation, including irritation of the skin around the mouth (rare).
- Changes are detected in laboratory test results, see section 'Tests and follow-up'.

**Side effects related to the active ingredient triamcinolone acetonide**

Burning, itching, irritation, 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.

<u>Side effects that may occur after prolonged use of corticosteroids for local treatment:</u>

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 related to the active ingredient lidocaine**

Very rare side effects (affect up to 1 in 10,000 users)

- local allergic reactions and non-local allergic reactions (such as burning, swelling, redness, hives, contact dermatitis, pain, rash)
- altered sense of taste
- numbness

**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 (<u>www.health.gov.il</u>) which links to an online form for reporting side effects. You can also use this link: <u>https://sideeffects.health.gov.il</u>

## 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.

## 6. ADDITIONAL INFORMATION

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

paraffin liquid, gelatin, pectin, carboxymethylcellulose sodium, polyethylene A-6.

**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.

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