Patient package insert in accordance with the pharmacists' regulations (preparations) – 1986

This medicine is to be supplied without 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 - "Further Information".

Read this leaflet carefully in its entirety 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. Below this age, contact a doctor.

You should use it in the correct manner. Consult a pharmacist if you need additional information. Contact a doctor if the disease signs (symptoms) are worsening 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

X Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients this medicine contains.
- There exist viral (such as herpes), fungal and/or bacterial infections of the mouth and/or throat or tuberculosis of the skin, especially during prolonged use of the preparation.

⚠ Special warnings regarding the use of 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 must be carried out under 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.

⚠ 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.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

⚠ Use of 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 or 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 SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The standard dosage 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 some 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!

Tests and follow-up:

A diagnostic (patch) 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.

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 drug or to reduce the frequency of use. Recovery of HPA axis function is generally immediate and complete upon discontinuation of therapy.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine at the required 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 each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Oracort E may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

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

- Irritation develops, including irritation of the skin around the mouth (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.

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

Cushing's syndrome, increased levels of blood sugar (hyperglycemia), glucosuria (detection of glucose in urine). 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 the attending doctor about any side effects and any additional medicines being taken by the child!

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the 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. FURTHER INFORMATION

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

Paraffin liquid, Gelatin, Pectin, Carboxymethylcellulose sodium, Polyethylene.

What does the medicine look and what are the contents of the package:

A yellow and viscous ointment, with a granular appearance. The medicine is marketed in tubes that contain 5 grams.

Manufacturer and license holder: Taro Pharmaceutical Industry Ltd., 14 Hakitor Street, Haifa Bay 2624761.

This leaflet was checked and approved by the Ministry of Health in December 2015.

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