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

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

ORACORT

Oral paste

Active ingredient - 1 gram of the preparation contains:
Triamcinolone Acetonide 1 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 correctly. 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 is indicated as an adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory and ulcerative lesions.

Therapeutic Group:
Synthetic corticosteroids for local treatment, with anti-inflammatory, antipruritic, and vasoconstrictive properties.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients this medicine contains.
- There exist viral (such as herpes simplex), 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 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 and adolescents must be carried out under medical supervision. Caution recommended when using in elderly patients.
- 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, 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.
- You suffer, or have suffered in the past from impaired liver function.

! If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.

! 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 or breastfeeding.

! Children
The safety and efficacy of using Oracort 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 THIS MEDICINE?

Check with the doctor or pharmacist if you are not sure.

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 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 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 medicine 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, 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 each 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 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 increased skin sensitivity, 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), detection of 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 in 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.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Mineral oil, fine gelatin powder, pectin, sodium carboxymethylcellulose, polyethylene.

What does the medicine look and what are the contents of the package:
A light tan paste, with a granular appearance.

The medicine is marketed in tubes that contain 5 grams.

Manufacturer: Taro Pharmaceuticals Inc., Ontario, Canada.

License holder: Taro International Ltd., 14 Hakitor Street, Haifa Bay, 2624761.

This leaflet was checked and approved by the Ministry of Health in August 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 01608.24803