

# ORREPASTE

Triamcinolone Acetonide (0.1% w/w)

## What is in this leaflet

1. What Orrepaste is used for
2. How Orrepaste works
3. Before you use Orrepaste
4. How to use Orrepaste
5. While you are using Orrepaste
6. Side effects
7. Storage and Disposal of Orrepaste
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

This leaflet answers some common questions about Orrepaste. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Orrepaste against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

## What Orrepaste is used for

Orrepaste is an oral paste used as adjunctive treatment and for temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.

## How Orrepaste works

Orrepaste contains triamcinolone, a corticosteroid.

Triamcinolone reduces the actions of chemicals in the body that cause inflammation, redness, and swelling.

Ask your pharmacist or doctor if you have any questions about this medicine.

## Before you use Orrepaste

### -When you must not use it

Allergic (hypersensitive) to Triamcinolone Acetonide and Propylene Glycol or any of the

ingredients listed at the end of this leaflet.

If you have tuberculosis (bacterial infection that mainly affects the lung), ulcer in digestive tract, diabetes, fungal, viral or bacterial infections of the mouth or throat.

If the packaging shows signs of tampering.

If the expiry date (EXP) printed on the pack has passed.

### -Before you start to use it

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

### -Taking other medicines

Inform your pharmacist or doctor if you are taking any other products (such as medicines purchased without a doctor's prescription, prescription medicines and herbal products) .

## How to use Orrepaste

### -How much to use

Apply a small dab (about ¼ inch) to the lesion at bedtime. It may be necessary to apply twice to three times daily depending on the severity of symptoms.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

### -When to use it

During bedtime.

### -How long to use it

Continue using Orrepaste for as long as your doctor recommends.

Review treatment in 7 days is required if significant regeneration or repair of oral tissues has not occurred.

### -If you forget to use it

Do not worry if you occasionally forget to use the product just carry on using it when you remember.

### -If you use too much (overdose)

Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effect such as hypothalamic-pituitary-adrenal axis suppression, manifestation of Cushing's syndrome (high level of hormone), hyperglycaemia (an excess of glucose in bloodstream) and glycosuria (excess sugar in urine).

If the hypothalamic-pituitary-adrenal axis suppression is found, then the medicine should be withdrawn, frequency of application reduced or a weaker steroid used.

Supplemental systemic corticosteroid may be required if signs and symptoms of steroid withdrawal occur.

## While you are using Orrepaste

### -Things you must do

If you become pregnant while you are using Orrepaste, tell your doctor. If you are about to start taking any new medicines, tell your doctor and pharmacist that you are using Orrepaste.

### -Things you must not do

Do not give Orrepaste to anyone else, even if they have the same condition as you.

When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroid may be absorbed in sufficient amounts to cause systemic effects. Discontinue use if local reactions develop. Normal body responses decreased in people receiving topical corticosteroid therapy.

### -Things to be careful of

Avoid contact with eyes

## Side effects

Like other medicines, Orrepaste can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

# ORREPASTE

Triamcinolone Acetonide (0.1% w/w)

---

Prolonged use may elicit the adverse reactions known to occur with systemic steroid preparation for example, adrenal suppression, and alteration of glucose metabolism, protein catabolism (protein degradation), ulcer activation in the digestive tract and others. These are usually reversible and disappear when the hormone is discontinued.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public→Reporting Medicinal Problem / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Orrepaste

### -Storage

For external use only.  
Store below 30°C.  
Keep out of reach of children.

### -Disposal

Dispose the medicine after the expiry date. Medicines should not be disposed of via wastewater or household waste, Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### -What it looks like

Orrepaste is a light green paste with mint flavour and odour.

Orrepaste is available in 5g aluminium tubes.

### -Ingredients

-Active ingredient(s):  
Each tube contains 0.1% w/w  
Triamcinolone Acetonide.

### -Inactive ingredients:

Quinoline Yellow, Brilliant Blue FCF, Sorbitol 70% Solution, Purified Water, Peppermint Oil, Pectin, Propylparaben, Methylparaben, Sodium Polyacrylate, Propylene Glycol, Sodium Carboxymethylcellulose

### -MAL number:

MAL19990624AZ

## Manufacturer

HOE Pharmaceuticals Sdn. Bhd.  
Lot 10, Jalan Sultan Mohamed 6,  
Bandar Sultan Suleiman,  
42000 Port Klang, Selangor,  
Malaysia.

## Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.  
Lot 10, Jalan Sultan Mohamed 6,  
Bandar Sultan Suleiman,  
42000 Port Klang, Selangor,  
Malaysia.

## Date of revision

-02/08/2017

## Serial Number:

BPFK(R4/1)240717/00183