Oroplus Gel

Lidocaine, Triamcinolone Acetonide, Chlorhexidine Hydrochloride (2.5%w/w, 0.1%w/w, 0.5%w/w)

What is in the leaflet

1. What Oroplus Gel is used for
2. How Oroplus Gel works
3. Before you use Oroplus Gel
4. How to take Oroplus Gel
5. While you are using it
6. Side Effects
7. Storage and Disposal of Oroplus Gel
8. Product Description
9. Manufacturer and product registration holder
10. Date of revision

What Oroplus Gel is used for

Oroplus Gel is an anaesthetic, antibacterial and anti-inflammatory agent, which is used in mouth infections or oral lesions. It heals and relieves pain and discomfort in acute and chronic lesions of the gum, palate, cheek and tongue.

How Oroplus Gel works

Lidocaine is a useful surface anaesthetic, rapidly absorbed through mucous membranes to stop pain and inflammation within a few minutes.
Triamcinolone Acetonide is a corticosteroid which works to reduce redness and swelling of damaged tissues.
Chlorhexidine has a broad-spectrum of activity against gram positive and gram-negative bacteria.

Before you use Oroplus Gel

- *When you must not take it*

Do not take this product if you are allergic (hypersensitivity) to Lidocaine Hydrochloride, Triamcinolone Acetonide, Chlorhexidine Hydrochloride and its derivatives.
Talk to your pharmacist or doctor if you are not sure whether you should start taking this medicine.

- *Before you start to use it*

Tell your pharmacist or doctor if you have allergies to any other medicines.

- *Taking other medicines*

Do not use any other product on the affected area without consulting your doctor.
Lidocaine when used in large quantities, repeatedly or swallowed is systemically absorbed and interacted with beta-adrenergic blocking agents, cimetidine and other amide local anaesthetic-derivative antiarrhythmic agents.
Long term administration of enzyme-inducing agents such as phenytoin may increase dosage requirements of Lidocaine.

How to take Oroplus Gel

- *How much to take*

Apply a small dab to the lesion 3 to 4 times daily after meals and at bedtime.

- *When to take it*

You should follow the recommended dose and should not take more than the prescribed dose.

- *How long to take it*

Take as directed by your doctor or pharmacist.

- *If you forget to take it*

If you missed a dose, apply the next dose as soon as you remember. Do not double the amount applied than needed.

- *If you take too much (overdose)*

In case you accidentally ingest too much of Oroplus Gel, contact your doctor immediately or your nearest hospital for medical advice.

While you are using Oroplus Gel

- *Things you must do*

Check with your doctor if symptoms persist or getting worse.

- *Things you must not do*

Do not take this product to treat any other conditions unless it has been prescribed by your doctor.

- *Things to be careful of*

Oroplus Gel contains chlorhexidine. Inform your healthcare provider if you have a known allergy to chlorhexidine.
Stop using this product and seek immediate medical assistance if you experience rash, itching, swelling, breathing difficulties, light-headedness or rapid heartbeat.
Oroplus Gel should be used with caution when there is local infection at area of treatment. Caution is also needed when there is severe traumatized mucosa as it may increase absorption of anaesthetic, leading to increased risk of systematic toxicity.
Herpes simplex at treatment site may be transmitted to other sites, including the eye and Oroplus Gel should be used with caution. Again, caution is needed in patients with anterior tooth restorations (front-tooth fillings) and periodontitis.

Side Effects

Immune system disorders
Frequency not known: Hypersensitivity including anaphylactic shock.
Side effects include skin rash, redness, itching, or hives, large, hive-like swellings on skin or in mouth or throat, burning, stinging, swelling, or tenderness.
Transient taste disturbances and a burning sensation of the tongue may occur on initial use.

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 npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Oroplus Gel

- *Storage*

- Store below 30°C.
- Protect from light and moisture.
- Keep out of reach of children.

Disposal

Do not take this after the expiry date. An expiry date is printed on the label and box of the medicine.

Product Description

- *What it looks like*

Oroplus Gel is a white to off white opaque gel with menthol flavour.

- *Ingredients*

Active ingredient
Lidocaine HCl 2.5%w/w, Triamcinolone Acetonide 0.1%w/w and Chlorhexidine HCl 0.5w/w.

Inactive ingredients
Sodium Saccharin, Sucralose, Poloxamer 407, Carbomer, Propylene Glycol, N-Methyl-2-Pyrrolidone, Aniseed Oil, Menthol, 1M NaOH Solution and Purified Water.

- MAL Number:

MAL00000000AZ

Manufacturer and Product Registration Holder

WINWA MEDICAL SDN. BHD.
1952, Lorong I.K.S. Bukit Minyak 3,
Taman I.K.S. Bukit Minyak,
14000 Bukit Mertajam,
Pulau Pinang, Malaysia.

Date of revision

16/06/2023

Serial Number:

NPRA(R4/1)XXXXXX/XXXXX