Title: Oroplus Gel - PI Date: 30 Dec 2022

OROPLUS GEL

Active Ingredients:
Lidocaine 2.5%w/w
Triamcinolone Acetonide 0.1%w/w
Chlorhexidine Hydrochloride 0.5%w/w

Presentation:
Tube of 8g.

Product Descriptions:
White to off white opaque gel with menthol flavour.

Pharmacology:
Lidocaine is a local anaesthetic of the amide type and used to block nerves from sending messages to the brain. It has a rapid onset of action and anaesthesia is obtained within a few minutes. It has an intermediate duration of action. Lidocaine is a useful surface anaesthetic, it may be rapidly and extensively absorbed through mucous membranes following topical application to stop pain and inflammation.
Triamcinolone Acetonide is a corticosteroid with mainly glucocorticoid activity in anti-inflammatory to reduce redness and swelling of damaged tissues.
Chlorhexidine is a very potent cationic chemoprophylactic agent that has a broad-spectrum of activity against gram positive and gram negative bacteria. It is both bacteriostatic and bactericidal depending on its concentration. The bactericidal effect, which is achieved at high concentrations, is due to the binding of the cationic to negatively charged bacterial cell walls and extramicrobial complexes. Bacteriostatic effect is achieved at low concentrations which causes an alteration of bacterial cell osmotic equilibrium and leakage of potassium and phosphorus.
Lidocaine is readily absorbed through damaged skin and from mucous membranes. Lidocaine is largely metabolized in the liver and about 90% is dealkylated to form monoethylglycinexylidine and glycinexylidine. Further metabolism occurs and metabolites are excreted in the urine with less than 10% of unchanged Lidocaine.
Corticosteroids are readily absorbed from the gastrointestinal tract. Triamcinolone is reported to have a half-life in plasma of about 2 to over 5 hours. It is bound to plasma albumin to a much smaller extent than hydrocortisone.
Chlorhexidine is poorly absorbed from gastrointestinal tract and skin.

Indications:
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.

Directions of Use: For oral topical use.
Apply a small dab to the lesion 3 to 4 times daily after meals and at bedtime.

Symptoms and Treatments of Overdose:
When use as recommended, overdosing with Oroplus Gel is rare.

Contraindication:
Do not use if known to be hypersensitive to Lidocaine Hydrochloride, Triamcinolone Acetonide or Chlorhexidine Hydrochloride.

Precautions:
Oroplus Gel contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is unknown, but available literature suggests this is likely to be very rare. **Oroplus Gel** should not be administered to anyone with a possible history of an allergic reaction to chlorhexidine.
If any signs or symptoms of a suspected hypersensitivity reaction such as itching, skin rash, redness, swelling, breathing difficulties, light headedness, and rapid heart rate develop, immediately stop using the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
If symptoms persist, please consult a doctor.

Use in Pregnancy and Lactation:
None known.

Interactions with Other Medicaments:
At recommended doses, drug interactions are uncommon. However in rare cases where if it is used in large quantities, used repeatedly or swallowed, lidocaine is systemically absorbed and interactions with beta-adrenergic blocking agents, cimetidine and other amide local anaesthetic-derivative antiarrhythmic agents have been reported. Long term administration of enzyme-inducing agents such as phenytoin may increase dosage requirements of lidocaine.

Undesirable Effects:
Immune system disorders.
Frequency not known: Hypersensitivity including anaphylactic shock.
Other side effects include allergic contact dermatitis (skin rash, redness, itching, or hives), angioedema (large, hive-like swellings on skin or in mouth or throat), burning, stinging, swelling, or tenderness not present before therapy. Transient taste disturbances and a burning sensation of the tongue may occur on initial use.

Storage:
Store below 30°C. Protect from light. Keep cap tightly closed.
Keep out of reach of children. Jauhkan daripada capaian kanak-kanak.

Shelf Life:
2 years from date of manufacture.

Manufacturer and Product Registration Holder
WINWA MEDICAL SDN. BHD.
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Size: 75mm x 110mm
Dark Blue (Pantone 2767U)