MUCO-AID LIQUID

NAME AND STRENGTH OF ACTIVE INGREDIENT(S):
MUCO-AID LIQUID
Each ml contains:
Lignocaine Hydrochloride……...25mg
Triamcinolone Acetonide……..1mg
Chlorhexidine Hydrochloride……...5mg

PRODUCT DESCRIPTION:
A white lotion with bubblegum and peppermint flavour.

PHARMACODYNAMICS :
Triamcinolone acetonide is used in dermatology for its anti-inflammatory, anti-pruritic and vasoconstrictive action on the skin or mucous membranes. It diffuses across cell membrane and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA (chromatin) and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various enzymes thought to be ultimately responsible for anti-inflammatory effects of topical application of triamcinolone acetonide, i.e. by its antimitotic activity. The mechanism by which the corticosteroids produce vasoconstriction is not known, and any relationship of this property to anti-inflammatory activity is obscure. The vasoconstrictor action may be a 'permissive' one, that is, the steroid permits or potentiates the action of endogenous substances with intrinsic vasoconstrictor activity (e.g. catecholamine) to exert their effects.
Lignocaine hydrochloride is an amide-type local anaesthetic, which blocks both the initiation and conduction of nerve impulses by decreasing permeability to sodium ions of, and thereby reversibly stabilising the neuronal membrane. This action inhibits the depolarisation phase of the neuronal membrane resulting in the failure of a propagated action potential and consequent conduction blockade.

PHARMACOKINETICS:
The absorption of topically applied triamcinolone acetonide depends on the physiological (e.g. degree of hydration) and anatomical (e.g. thickness) characteristic of the region of the skin to which it is applied. Once the drug reaches the dermis, it is absorbed into the systemic circulation, particularly when the skin is broken.
There is some systemic absorption of topical corticosteroids through the oral mucosa; absorption increases with increased potency. Once the drug is absorbed into the systemic circulation, it is bound to the plasma proteins. It is mainly metabolised in the liver but also in the kidney and is excreted in the urine. Lignocaine hydrochloride is readily absorbed through mucous membranes into the systemic circulation. The rate of absorption is influenced by the vascularity or rate of blood flow at the site of application and the total dosage administered.
Lignocaine undergoes first-pass metabolism in the liver and bioavailability is about 35% after oral administration. Metabolism in the liver is rapid and approximately 90% of a given dose is dealkylated to form monoethylglycinexylidine (MEGX) and glycinexylidide (GX). Both of these metabolism may contribute to the therapeutic and toxic effects of lignocaine. Further metabolism occurs and metabolites are excreted in the urine with less than 10% of unchanged lignocaine. Lignocaine readily crosses the placenta and blood-brain barrier; it is excreted in breast milk.

INDICATION:
It is indicated for the relief of discomfort and pain, for the reduction of inflammation and to promote healing in the following conditions: ulcer, lesions and soreness in the gums, tongue, lips or palate; trauma or lesions in the oral cavity caused by new denture, denture sore spots and denture stomatitis; and teething disorders.

RECOMMENDED DOSAGE:
Instill 2-4 drops of lotion to the lesion by using the tip of a clean cotton bud or finger. Rub gently to cover the lesion with lotion. Application may be repeated after 1-2 hours, preferably after meal, and at bedtime.

ROUTE OF ADMINISTRATION:
For external use.

CONTRAINDICATIONS:
1. It is contraindicated in herpetic lesions of known viral origin such as herpes labialis, intraoral lesions such as primary herpetic gingival stomatitis, herpanginas, and in the presence of infection.
2. Known hypersensitivity to any ingredient of the preparation.

WARNINGS AND PRECAUTIONS:

1. Care should be taken in patients with tuberculosis, peptic ulceration, or diabetes mellitus, especially in long term usage.
2. Since adrenal suppression and growth retardation due to the systemic absorption of topical corticosteroid have been documented in children, special care must be exercised in using cortecosteroid in the paediatric patients, especially when extensive areas are treated.
3. If significant regeneration or repair of oral tissues has not occurred in 7 days, additional investigations into the aetiology of oral lesion are advised.
4. It should be borne in mind that the normal defensive responses of the oral tissues are depressed in patients receiving topical corticosteroid therapy.
5. Risk-benefit must be considered in women of childbearing potential and particularly during early pregnancy or nursing mothers.
6. Caution is advised in paediatric, geriatric, acutely ill, or debilitated patients, who may be more susceptible to systemic toxicity of this product.
7. Do not chew gum or food while numbness persists because of risk of biting tongue or buccal mucosa.
8. Do not eat for one hour following use of medication because it may impair swallowing leading to risk of aspiration.
9. Muco-Aid Liquid contains chlorhexidine hydrochloride. Chlorhexidine hydrochloride 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. Muco-Aid Liquid should not be administered to anyone with a possible history of an allergic reaction to chlorhexidine.
10. 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.
11. This product cannot be instilled in to ear.

INTERACTIONS WITH OTHER MEDICAMENTS:

1. **Beta-adrenergic blocking agents:** : Concurrent use may slow metabolism of lignocaine because of decreased hepatic blood flow, leading to increase risk of lignocaine toxicity, especially with large doses, repeated administration, oral use (especially if swallowed) of lignocaine.
2. **Cimetidine:** Cimetidine may inhibit hepatic metabolism of lignocaine, leading to increase risk of lignocaine toxicity, especially with large doses, repeated administration, or oral use (especially if swallowed) of lignocaine.
3. It should be remembered that corticosteroid-induced adrenal suppression has been associated not only with systemic therapy, but has followed topical application of corticosteroid preparations, particularly those containing potent corticosteroids. Adrenal suppression has also been associated with the use of inhalants and the topical application of eye drops, eye ointments, and nasal preparations. Systemically absorbed topical corticosteroid may interact with concurrent drug therapy given to patients.
4. **NSAIDs:** Concomitant administration of ulcerogenic drugs such as indomethacin during corticosteroid therapy may increase risk of gastro-intestinal ulceration. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinemia. Although concomitant therapy with salicylates and corticosteroids does not appear to increase the incidence or severity of gastro-intestinal ulceration, the possibility of this effect should be considered.
5. **Potassium-depleting Drugs:** Potassium-depleting diuretics (e.g. thiazides, frusemide, and ethacrynic acid) and other drugs that deplete potassium, such as amphotericin B, may enhance the potassium wasting effect of corticosteroid. Serum potassium should be closely monitored in patients receiving corticosteroids and potassium-depleting drugs.
6. **Anticholinesterase Agents:** Interaction between corticosteroids and anticholinesterase agents such as ambinonium, neostigmine, or pyridostigmine (and presumably organophosphate anticholinesterase pesticides) can produce severe weakness in patients with myasthenia gravis. If possible anticholinesterase medication should be withdrawn at least 24 hours prior to initiation of corticosteroid therapy.

PREGNANCY AND LACTATION:

Pregnancy

No clinical data on pregnancies are available. Muco-Aid Liquid should be used during pregnancy only when clearly needed.

Lactation

There are no clinical data on the excretion of chlorhexidine or triamcinolone into breast milk but lignocaine could be excreted into breast milk. So, Muco-Aid Liquid need to be used with caution and on doctor's advice in nursing women.

SIDE EFFECTS:

Signs of infection such as pain, redness or pus-containing blister and/or signs of irritation such as burning, itching, blistering or peelings not present before therapy. (These may require medical attention).

Systemic absorption due to long term use may cause systemic corticosteroid effects including Cushing's syndrome, hyperglycaemia, and glycosuria.

Immune system disorders. Frequency not known: Hypersensitivity including anaphylactic shock.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Although the bioavailability of lignocaine is low, it may be sufficient and there have been reports of central nervous system toxicity, seizures and death in children and adult following the ingestion of topical solution and after the use of viscous preparation in the mouth.

Symptoms:

Accidental excessive ingestion may lead to excessive absorption of lignocaine. These may present as blurred or double vision, or combine; dizziness; tinnitus; shivering or trembling; increased sweating; hypotension; slow or irregular heartbeat; unusual paleness due to cardiovascular system depression, which may lead on to cardiac arrest; central nervous system stimulation with symptoms of unusual anxiety, excitement, nervousness and restlessness, and convulsion, followed by central nervous system depression presented with drowsiness which may lead to unconsciousness and respiratory arrest; and death.

Treatment:

Activated charcoal has been suggested for use in the treatment of oral overdosage with lignocaine. The use of gastric lavage has also been suggested but this could be hazardous if convulsion is imminent. Acidification of the urine has been used to increase renal excretion of lignocaine but any increase is likely to be of any significance.

Supportive and symptomatic steps should be taken to maintain the circulation and respiration and to control convulsion. Vasopressor agents have been suggested in the treatment of marked hypotension although their use is accompanied by a risk of central nervous system excitation. Vasopressors should not be given to patients receiving oxytocic drugs.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:

No influence on the ability to drive and use machine.

PRECLINICAL SAFETY DATA:

Not applicable

INSTRUCTION FOR USE:

To be used topically, to the oral mucosa.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage Form: Lotion
Packing Size: 8g in plastic bottle; 24 x 8g in carton box.

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN. BHD.
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

11/12/2019