B GARGLE SOLUTION 0.15%W/V

Anti-inflammatory, analgesic solution for use as gargle / rinse / mouthwash.

PHARMACOLOGY:

Benzydamine is an anti-inflammatory analgesic agent. Chemically it is a base whereas other non steroidal anti-inflammatory agents are acids.
Systemic administration in animal model showed that benzydamine is effective against pain and oedema due to inflammatory conditions. It inhibits granuloma formation.
When administrated orally to rats at doses up to 100mg/kg, benzydamine does not cause erosion of the gastric mucosa and it gives local anaesthetic action when used at concentration for topical treatment.
Benzydamine has more analgesic activity in inflammatory condition rather than in non inflammatory pain. Benzydamine posseses an anti-pyretic effect in common with the aspirin like drugs.
The mechanism of action for anti-inflammatory property is by inhibiting the biosynthesis of prostaglandins and may also by stabilising the cellular membranes, but not related to stimulation of the pituitary –adrenal axis.

PHARMACOKINETICS:

Absorbtion

Oral doses of benzydamine are well absorbed and peak plasma drug concentration is attained fairly rapidly and then declined with a half life of about 13 hours. Upon topical administration benzydamine is well absorbed into the inflammed oral mucosa and produces anti-inflammatory and local anaesthetic action. Plasma drug concentration are low and parallel the amount actually ingested.

Excretion

Benzydamine and its metabolites are excreted largely in urine. Benzydamine is metabolised by oxidation, conjugation and dealkylation.
Benzydamine was detected in blood and urine after gargling and mostly eliminated in the first 24 hours. Benzydamine accumulation in plasma was not seen upon repeated adminstration for 7 days.

COMPOSITION:

Benzydamine Hydrochloride 0.15%w/v.

INDICATIONS:

It is indicated for the relief of painful conditions of the oral cavity including: tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post orosurgical and periodontal procedures.

ROUTE OF ADMINISTRATION

Topically use as gargle/mouthwash/rinse.

DOSAGE AND ADMINSTRATION:

Generally used undiluted, but if stinging occurs it may be diluted with water. The solution should be expelled from the mouth after use. Uninterrupted treatment should not exceed seven days.
Adults: 15mL (approximately one tablespoon) gargled or rinsed in the mouth for at least 30 seconds, 1½ to 3 hourly as required.
Children: 5-15mL as gargle if able to do so or as an oral rinse. Not recommended in children under 6 years of age.
Elders: No special dosage recommendations are made for elderly patients.
Use with caution in patients with impaired renal or hepatic function.

ADVERSE EFFECTS:

Commonly observed reaction is numbness in oral cavity and occasionally burning or stinging sensation. Other local adverse effects were less common included dryness or thirst, tingling, warm feeling in mouth and altered sense of taste. The systemic adverse reactions were very uncommon and never of serious nature

which consisted mainly of nausea, vomiting, retching, gastro-intestinal disorder, dizziness, headache and drowsiness. Hypersensitivity reactions occur very rarely but may be associated with pruritis, rash, urticaria, photodermatitis and occasionally laryngospasm or bronchospasm.

INTERACTION WITH OTHER MEDICAMENTS:
None known.

WARNINGS AND PRECAUTIONS:
It should not be swallowed but rather should be expectorated after each use. Generally used undiluted but if stinging occur, it may be diluted with water. If a sore throat is caused by a bacterial infection, appropriate antibacterial therapy should be taken. Should be used with caution in patients with hepatic or renal impairment.
Due to lack of enough clinical experience, not recommended in children under 6 years of age. Hypersensitivity reactions due to the product or any of its ingredients may occur in susceptible individuals. Avoid contact with eyes.
This product contains aspartame and hence unsuitable for phenylketonurics.

PREGNANCY AND LACTATION:
There is no evidence on safety of benzydamine hydrochloride in pregnant patients. Risk to benefit ratio should be established if to be used in these patients.

CONTRAINDICATION:
Contraindicated in patients with known hypersensitivity to benzydamine or any of the ingredients.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Benzydamine gargle is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. There is no specific antidote for benzydamine and should excessive quantities be ingested the treatment should be symptomatic.

PHARMACEUTICAL INFORMATION/PACKAGE:
Description : A green colour solution with lime flavour.
Packing Size : Each amber plastic bottle contains 100ml of Benzydamine Gargle Solution 0.15%w/v.
Storage : Store in the original package and in a dry place.Do not store above 30°C. Protect from light. Keep out of reach of children.
Shelf-Life : Three years from the manufacturing date.

PRODUCT REGISTRATION HOLDER / MANUFACTURER:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas, Pulau Pinang,
Malaysia.

14 August 2015