Dichlorobenzyl Alcohol
Amylmetacresol
Lidocaine Hydrochloride

Trosoothe Plus

1.2 mg/600 mcg/10 mg Lozenge (Lemon Flavor)
ANTISEPTIC/ANESTHETIC

FORMULATION:
Each lozenge contains:
Dichlorobenzyl Alcohol EP .....1.2 mg
Amylmetacresol BP .....600 mcg
Lidocaine Hydrochloride BP ..... 10 mg

PRODUCT DESCRIPTION:
Yellow, round biconvex lozenges with occasional presence of entrapped air bubbles and rough edges.

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Throat Preparations; Antiseptics; R02AA03 Dichlorobenzyl alcohol 2,4-Dichlorobenzyl Alcohol and Amylmetacresol have antiseptic properties. Lidocaine is a local anaesthetic of the amide type, acting to produce reversible loss of sensation by preventing or diminishing the generation and transmission of sensory nerve impulses near the site of application.
Depolarisation of the neuronal membrane and ion exchange are reversibly inhibited. It provides an anaesthetic effect by blocking neuronal transmission.

PHARMACOKINETIC PROPERTIES
Lidocaine is readily absorbed from mucous membranes. The plasma elimination half life is about 2 hours.

Lidocaine undergoes significant first pass metabolism in the liver and is rapidly de-ethylated to the active metabolite and then hydrolysed to various metabolites including glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

2, 4-Dichlorobenzyl alcohol is metabolized by the liver to form hippuric acid which is excreted in the urine.

No data available on amylmetacresol metabolism and elimination.

INDICATION:
Trosoothe Plus Lozenges are indicated for the symptomatic relief of mouth and throat infections including severe sore throat.
Trosoothe Plus Lozenges is indicated in adults and children over 12 years of age.

DOSAGE AND ADMINISTRATION:
Posology
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Adults
One lozenge to be sucked slowly every two hours as required. No more than 8 lozenges to be sucked in any 24 hours.

Pediatric Population
Children over 12 years:
As above for adults.

Children under 12 years:
Not recommended for children under 12 years.

Elderly
There is no need for dosage reduction in the elderly.

Method of administration
For oromucosal administration. To be dissolved slowly in the mouth.
Dissolve one lozenge in the mouth every 2 to 3 hours or as prescribed by the physician.
If symptoms persist, consult your doctor.

CONTRAINDICATION:
Trosoothe Plus Lozenges are contraindicated in persons who have previously shown hypersensitivity to any of the active ingredients or to any of the excipients.
A history of allergy to local anesthetics of the amide type.
In patients who have a history of or are suspected to have methaemoglobinaemia.

WARNINGS AND PRECAUTIONS:
Not recommended for children under 12 years.
This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One lozenge contains no more than 19.60 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'. This medicine contains 0.98 g glucose and 1.52 g sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

This medicine contains fragrance with Anisyl alcohol, d-Limonene and linalool which may cause allergic reactions.

Also contains sulphites – Sulphur Dioxide (E220) which rarely cause severe hypersensitivity reactions and bronchospasm.

Warning:
Do not exceed the stated dose.
Consult your doctor within 3 days if symptoms persist or are accompanied by high fever or headache, or if anything unusual happens.
Consult your doctor before taking this product if you are pregnant or breastfeeding.
Consult your doctor if you suffer from asthma or bronchospasm.
This product may cause numbness of the tongue and therefore care should be taken in eating and drinking after taking the lozenge.

PREGNANCY AND LACTATION
Pregnancy
The safety of this medicinal product for use in human pregnancy has not been established. A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity of lidocaine. There are no or limited amount of data from the use of amylmetacresol and 2, 4-dichlorobenzyl alcohol. The product is therefore not recommended during pregnancy except under medical supervision.

Lactation
Lidocaine metabolites are excreted in human milk but the therapeutic doses of the product, no effects on the breastfed newborns/infant are anticipated. There is insufficient information on the excretion of amylmetacresol or 2,4-dichlorobenzyl alcohol metabolites in human milk.
A risk to newborns/infants cannot be excluded. The product is therefore not recommended during lactation except under medical supervision.

Effects on ability to drive and use machines
No adverse effects are known.

DRUG INTERACTION:
While a number of interactions are theoretically possible with lidocaine, these drug interactions are unlikely to be clinically relevant to the safety of the patient as the product is administered topically.
The toxicity of oral lidocaine may be increased when the drug is taken in combination with the following drugs:

- CYP34A inhibitor drugs (e.g. erythromycin, itraconazole and ketoconazole)
- CYP1A2 inhibitor drugs (e.g. fluvoxamine and cimetidine)
- Beta blockers
- Other antiarrhythmic drugs (e.g. mexiletine)

Adverse Reaction:
Adverse events which have been associated with amylmetacresol, 2, 4-dichlorobenzyl alcohol and lidocaine are given below tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (<1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Not known	Hypersensitivity*
Gastrointestinal Disorders	Not known	Nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash

Overdose and Treatment:
In view of the nature and presentation of Trosoothe Plus Lozenges, accidental or deliberate overdosage is unlikely.

Symptoms
Overdosage will initially produce excessive anaesthesia of the upper alimentary tract and should not present a problem other than gastrointestinal discomfort. The most serious effects of lidocaine intoxication are on the central nervous system and cardiovascular system and may also include methaemoglobinaemia, severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest and death.

Management
Treatment of potentially toxicological overdose should be symptomatic and supportive and conducted under medical supervision.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

Keep all medicines out of reach of children.

AVAILABLITY:
Alu/ Clear PVC Blister Pack x 12's (Box of 24's)

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