

## STREPSILS® MAX PLUS LOZENGE

### COMPOSITION:

Each lozenge contains:

|                          |        |
|--------------------------|--------|
| Amylmetacresol           | 0.6mg  |
| Dichlorophenylcarbinol   | 1.2mg  |
| Lignocaine hydrochloride | 10.0mg |

### DESCRIPTION

Pale blue-green, circular lozenge with a characteristic aromatic flavour. Available in unit cartons containing 2 blisters of 8 lozenges.

### PHARMACODYNAMICS

2,4-Dichlorobenzyl alcohol (Dichlorophenylcarbinol) and Amylmetacresol have antiseptic properties. Lidocaine (Lignocaine) 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.

### PHARMACOKINETICS

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 metabolites including glycineylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine. 2,4-Dichlorobenzyl alcohol (Dichlorophenylcarbinol) is metabolised by the liver to form hippuric acid which is excreted in the urine. No data available on amylmetacresol metabolism and elimination.

### INDICATION

For the symptomatic relief of mouth and throat infections including severe sore throat.

### DOSAGE AND ADMINISTRATION

For Oral Use only.

Adults and children over 12 years - one lozenge to be sucked every 2 hours as required. Not more than 8 lozenges to be sucked in any 24-hour period. Not recommended for children under 12 years of age.

### CONTRAINDICATION

Strepsils Max Plus lozenge 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 anaesthetics of the amide-type. In patients who have a history of or are suspected to have methaemoglobinaemia. Patients suffering from asthma or bronchospasm. Children under 12 years of age.

### WARNING AND PRECAUTIONS

Consult your doctor if symptoms persist after 3 days, or are accompanied by a high fever or headache. Consult your doctor before taking this product if you are pregnant or breast-feeding. Patients with rare glucose-galactose malabsorption should not take this medicine.

### INTERACTIONS WITH OTHER MEDICAMENTS

While a number of interactions are theoretically possible with lidocaine, these drug interactions are unlikely to become clinically significant to the safety of the patients 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:

- Erythromycin
- Itraconazole
- Cimetidine
- Fluvoxamine
- Beta blockers
- Other antiarrhythmic drugs (e.g. Mexiletine)

### PREGNANCY AND LACTATION

The safety of Strepsils Max Plus during pregnancy and lactation has not been established. Strepsils Max Plus is not recommended for pregnant and nursing mothers unless the expected benefits to the mother outweigh the potential risk to the neonate.

### ADVERSE REACTIONS

May occasionally cause allergic reactions. Abnormal taste and burning sensation of the throat have been reported.

### OVERDOSE

Overdosage will initially only produce excessive anaesthesia of the upper alimentary tract. However, lidocaine intoxication can result in severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest and death. In view of the nature and presentation of Strepsils Max Plus lozenges, accidental or deliberate overdosage is highly unlikely. Treatment of potentially toxicological overdose should be symptomatic and supportive and conducted under medical supervision.

### STORAGE CONDITION

Store in a dry place, below 30°C

### SHELF LIFE

3 years

### MANUFACTURED BY

Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd.,  
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### PRODUCT REGISTRATION HOLDER

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