147 mm

31 mm

13 mm

92.5 mm

260 mm

62.5 mm

62 mm

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MALAYSIA

CO-PHENYLCAINE FORTE

PRODUCT INFORMATION

ACTIVE INGREDIENTS

Lignocaine HCl ..... 50 mg/mL
Phenylephrine HCl ..... 5 mg/mL

Inactive Ingredients

Sodium phosphate monobasic, sodium metabisulfite, disodium edetate and benzalkonium chloride
Sodium hydroxide or citric acid (to adjust pH)

Product Description

A clear transparent liquid free from particulate matter.

Pharmacology:

a) **Lignocaine Hydrochloride:** This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for 1 hour. It does not produce irritation to mucous membranes due to its non-ester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

b) **Phenylephrine Hydrochloride:** This is a sympathomimetic agent with mainly direct effects on the alpha adrenoreceptors. The phenylephrine in Co-Phenylcaine Forte constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Indications:

- Preparation of nasal mucosa for surgery
- Aid the treatment of acute nose bleeds and removal of foreign bodies from the nose
- Topical anaesthesia of the pharynx prior to direct or indirect laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper airways

Contraindications:

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy
- Children under 2 years of age

Precautions:

- Elderly and debilitated patients should be given reduced dosages.
- Eating and drinking: the use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within 2 hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.
- This preparation contains sodium metabisulfite that may cause serious allergic reaction in certain susceptible patients. Do not use if known to be hypersensitive to bisulphate.
- Patients with cardiovascular diseases. Co-Phenylcaine Forte should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

  There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2mmH systolic and 7.5mmHg diastolic) lasting for 10 minutes after the administration of this medication to healthy individuals. **(Stott S et al. Australian Journal of Hospital Pharmacy Vol 25 No 5 1995 page 147 Cardiovascular Effects of Nasal Co-Phenylcaine Forte Spray)** This must be taken into account if this medication is given to hypertensive patients.
- Patients with impaired kidney or liver function. Lignocaine is metabolized in the liver and must be given with caution to patients with hepatic insufficiency. Metabolites of lignocaine may accumulate in patients with renal impairment.
- Asthmatic patients: This preparation contains sodium metabisulfite. A sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than non-asthmatic people.
- General precautions: genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.
- Use in pregnancy and lactation. Co-Phenylcaine Forte should not be used in pregnancy (See Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2. Co-Phenylcaine Forte Spray may be used as directed in breast-feeding mothers.

Interactions:

- Propranolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be observed closely.
  Antiarrhythmic drugs - lignocaine can have additive effects or antagonistic effects.
  Suxamethonium - lignocaine prolongs the action of suxamethonium.
  Phenytoin- lignocaine and phenytoin have additive cardiac depressant effects.
  Antidepressants - may interact with phenylephrine.

Adverse Reactions:

Phenylephrine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or discrimination may occur following rapid absorption of Lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing.

Dosage and Administration:

Route of Administration: **Nasal or pharyngeal**

- Do not exceed the recommended dosage regimes.
- Do not administer to children under 2 years of age.
- Doses are to be administered once only.

2-4 years ..... 1 squirt per nostril
4-8 years ..... 2 squirts per nostril
8-12 years ..... 3 squirts per nostril
Adults & Children over 12 years ..... 5 squirts per nostril

Each squirt measures 100 microlitres.
A new spray nozzle must be used for each patient.

Overdosage:

Symptoms of overdosage: Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and in more severe cases convulsions. Toxicity due to alpha adrenergic over stimulation may result in tachycardia and arrhythmia.
Treatment: Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathologic arrhythmias.

Dosage Form:
Pump actuated Topical Spray

Dosage Strength:
Each dosage spray measures 100 microlitres and delivers
Lignocaine ..... 5 mg
Phenylephrine ..... 0.5 mg

Storage Conditions:
Store below 30° C.

Packing Size:
Round 50 mL HDPE plastic bottle with spray attachment.

Name and address of Product Owner:
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Technical Specifics

Item Code:
- Item Code to be positioned in allocated area