Chlorpheniramine Maleate (1mg) + Paracetamol (125mg) + Phenylephrine (2.5mg)

Coldstave P Oral Drops

Chlorpheniramine Maleate (1mg) + Paracetamol (125mg) + Phenylephrine (2.5mg) Drops

Composition

Each 1 ml of the drop contains:

- Chlorpheniramine Maleate 1 mg
- Paracetamol 125 mg
- Phenylephrine 2.5 mg

Excipients:

• Suitable excipients as per formulation requirements.

Description

This combination drop contains Chlorpheniramine Maleate, an antihistamine, Paracetamol, an analgesic and antipyretic, and Phenylephrine, a decongestant, offering relief from cold, flu, and allergy symptoms. Chlorpheniramine Maleate helps control sneezing, runny nose, and watery eyes, while Paracetamol reduces fever and relieves mild to moderate pain. Phenylephrine works as a decongestant to relieve nasal congestion by narrowing blood vessels in the nasal passages.

The drop formulation is suitable for children and adults for symptomatic relief from cold, allergic rhinitis, sinusitis, and related conditions.

Indications

- Common Cold: For relief from nasal congestion, sneezing, and body aches.
- Allergic Rhinitis: To alleviate symptoms such as sneezing, runny nose, and itching.
- Sinusitis: To relieve nasal congestion and sinus pressure.

• Hay Fever: For the symptomatic relief of allergic reactions causing sneezing, watery eyes, and nasal congestion.

Dosage and Administration

- Adults and children over 12 years:
 - Take 10-20 drops (0.5-1 ml) every 4 to 6 hours as needed.
 - Maximum dose: 60 drops (3 ml) per day.
- Children (6-12 years):
 - Take 5-10 drops (0.25-0.5 ml) every 4 to 6 hours as needed.
 - Maximum dose: 30 drops (1.5 ml) per day.
- Children (2-6 years):
 - Take 2-5 drops (0.1-0.25 ml) every 4 to 6 hours as needed.
 - Maximum dose: 15 drops (0.75 ml) per day.

Note: The dosage should be adjusted according to the patient's age, weight, and specific medical condition. Please follow the advice of your healthcare provider for appropriate dosing.

Mechanism of Action

- Chlorpheniramine Maleate: An antihistamine that blocks histamine receptors (H1), reducing symptoms like sneezing, itching, and runny nose caused by allergic reactions.
- Paracetamol: An analgesic and antipyretic that works by inhibiting prostaglandin production, providing relief from pain and reducing fever.
- Phenylephrine: A sympathomimetic drug that acts as a decongestant, narrowing blood vessels in the nasal passages, which reduces swelling and improves airflow through the nose.

Contraindications

- Hypersensitivity to chlorpheniramine, paracetamol, phenylephrine, or any of the excipients in the formulation.
- Severe hypertension: Use with caution in patients with high blood pressure due to the phenylephrine content.
- Severe liver disease: Caution is advised for patients with liver dysfunction, as paracetamol is metabolized in the liver.
- Severe cardiovascular conditions: Use with caution in patients with heart conditions, as phenylephrine may increase heart rate and blood pressure.
- Glaucoma: Caution is advised for patients with glaucoma, particularly angle-closure glaucoma.

Warnings and Precautions

- Sedation: Chlorpheniramine Maleate can cause drowsiness. Caution should be exercised when performing tasks requiring mental alertness, such as driving or operating machinery.
- Cardiovascular Risk: Phenylephrine may cause an increase in blood pressure and heart rate, which could be problematic in patients with cardiovascular conditions.
- Liver Disease: Paracetamol should be used with caution in patients with liver disease, as overdose can cause liver damage.
- Renal Impairment: Use with caution in patients with kidney disease, especially when taking high doses of paracetamol.
- Pregnancy and Lactation: Consult a healthcare provider before using this medication during pregnancy or breastfeeding. Chlorpheniramine can pass into breast milk, and phenylephrine should be used with caution during breastfeeding.

Side Effects

Common Side Effects:

- Drowsiness or dizziness
- Nausea or upset stomach
- Dry mouth
- Increased heart rate or palpitations

Lightheadedness or dizziness

Serious Side Effects (rare):

- Severe allergic reactions (e.g., rash, swelling, difficulty breathing)
- Increased blood pressure or heart rate
- Liver damage (from paracetamol overdose)
- Severe drowsiness or confusion, particularly in elderly patients
- Difficulty urinating

Drug Interactions

- Monoamine Oxidase Inhibitors (MAOIs): Do not use with MAOIs or within 14 days of stopping them.
- CNS Depressants: Taking this medication with alcohol, sedatives, or tranquilizers may increase the sedative effects, leading to excessive drowsiness.
- Antihypertensive Medications: Phenylephrine may counteract the effects of blood pressure-lowering medications.

Storage

- Store at room temperature (15°C to 30°C).
- Keep in a cool, dry place away from direct light and moisture.
- Keep the bottle tightly closed when not in use.
- Keep out of the reach of children.

Note: Always use this medication as directed by your healthcare provider. If you experience any unusual side effects or symptoms, stop using the medication and seek immediate medical attention.

Manufactured in India for:



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