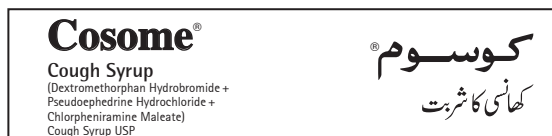


<b>Artwork:</b>		
Cosome Cough Syrup Leaflet		
Article No.	13002652	Ver. 00
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<b>Artwork Description:</b>	
Size: WxH:	82.5mm x 210mm
Colors :	■ Pantone Black C



#### 1. COMPOSITION

Each 5 ml contains:

Dextromethorphan Hydrobromide USP ..... 10 mg

Pseudoephedrine Hydrochloride USP ..... 30 mg

Chlorpheniramine Maleate USP ..... 2 mg

#### 2. DESCRIPTION

Dextromethorphan hydro bromide monohydrate is a salt of the methyl ether dextrorotatory isomer of levorphanol a narcotic analgesic. Pseudoephedrine is a sympathomimetic amine commonly used as a decongestant. Chlorphenamine maleate is absorbed slowly from the gastrointestinal tract, with peak plasma concentrations occurring about 2.5 to 6 hours after oral administration. Chlorphenamine appears to undergo considerable first-pass metabolism.

#### 3. THERAPEUTIC INDICATIONS

Recommended for the temporary relief of symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- Runny nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes
- Relief of symptoms of dry cough
- Cough due to minor throat and bronchial irritation
- Nasal congestion
- Reduces swelling of nasal passages

#### 4. DOSAGE & ADMINISTRATION

- Children 6 to 12 years: ½-1 teaspoon three times daily or as prescribed by the physician. Parents or care givers should seek medical attention if the child's condition deteriorates.
- Adults: 2 Teaspoon full 3 times daily or as prescribed by the physician. It should not be used for more than 5 days without doctor's advice.

#### 5. CONTRAINDICATIONS

- Cosome contraindicated in patients with a known hypersensitivity to any of the ingredients.
- Severe hypertension, coronary artery disease, bronchial asthma, narrow angle glaucoma.
- Cosome is contraindicated in epileptics because of the antihistamine content and in patients currently taking or within 2 weeks of stopping monoamine oxidase inhibitors.
- Contraindications for the use of pseudoephedrine include: concomitant or recent (previous 14 days) monoamine oxidase inhibitor (MAOI) therapy, severe or uncontrolled hypertension, and/or severe coronary artery disease.
- Atopic children should be administered dextromethorphan only under the strict supervision of a health care professional.
- The concomitant use of a dextromethorphan-containing product and monoamine oxidase inhibitors can occasionally result in symptoms such as hyperpyrexia, hallucinations, gross excitation or coma.
- Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to subjects in, or at risk of developing respiratory failure.
- Children below the age of 6 years.

#### 6. SPECIAL WARNINGS & PRECAUTIONS FOR USE

- Do not use for more than 5 days even if the symptoms persist.
- Patient with asthma should consult a medical practitioner before using this product.
- Do not use if cough is accompanied by excessive sputum.
- Avoid driving or working near machinery
- Use with caution in patients with renal impairment, urinary retention, diabetes, prostate enlargement, hyperthyroidism, glaucoma, hepatic impairment or organic

- cardiac disease and those taking other sympathomimetic agents, such as decongestants, amphetamine-like psychostimulants and appetite suppressants.
- People with bipolar disorder, using antipsychotics should use care when taking pseudoephedrine, as it can cause insomnia and thus trigger a manic episode
- Caution should be taken in atopic children.
- The effects of single dose of Cosome on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. As with other sympathomimetic agents, caution should be exercised in patients with prostatic enlargement or bladder dysfunction.
- In severe hepatic or renal dysfunction, a single dose of Cosome should be given, and the patient's response used as a guide to the dosage requirement for further administration.
- Patients suffering from chronic cough as occurs with smoking, asthma or patients suffering from an acute asthma attack, or where cough is accompanied by excessive secretions should be advised to consult a Healthcare Professional before use.

#### 7. ADVERSE REACTIONS

**Pseudoephedrine hydrochloride:** Pseudoephedrine may cause anxiety, tremor, cardiac arrhythmias, palpitations, tachycardia, hypertension, nausea, vomiting, and headache and may occasionally cause insomnia and urinary retention in men. Rarely sleep disturbance and hallucinations have been reported. There have been rare cases of psychosis following misuse of pseudoephedrine.

**Chlorphenamine maleate:** Chlorphenamine may cause drowsiness, nausea, vomiting, headaches, blurred vision, anorexia and dryness of the mouth. The administration of antihistamines has also been associated with rash, angioedema, convulsions, paresthesias, dizziness and constipation.

**Dextromethorphan hydro bromide:** Adverse effects are rare; however, the following side effects may be associated with dextromethorphan hydro bromide: Gastrointestinal upset, diarrhea, dizziness and hypersensitivity.

#### 8. DRUG INTERACTIONS

The following interactions with have been noted:

- The antibacterial agent furazolidone is known to cause progressive inhibition of monoamine oxidase and although there are no reports of a hypertensive crisis having occurred, it should not be administered concurrently with Cosome.
- There may be an increased risk of arrhythmias if pseudoephedrine is given to patients receiving cardiac glycosides or tricyclic antidepressants. Pseudoephedrine may reduce the hypotensive effect of antihypertensive with sympathomimetic activity. Concurrent use of pseudoephedrine with monoamine oxidase inhibitors may cause a hypertensive crisis. Chlorphenamine may enhance the sedative effects of CNS depressants, including alcohol, barbiturates, hypnotics, anxiolytics, sedatives and antipsychotics. As chlorphenamine possesses anticholinergic activity the effects of some anticholinergics may be potentiated.
- Quinidine can increase serum concentrations of dextromethorphan markedly and some patients have experienced symptoms of dextromethorphan toxicity when the two agents have been used together.
- Amiodarone appears to be able to increase serum concentrations of dextromethorphan.
- CYP2D6 inhibitors can increase the effects of dextromethorphan. Examples of these include chlorpromazine, delavirdine, fluoxetine, miconazole, paroxetine, pergolide, quinidine, quinine, ritonavir, and ropinirole.
- Chlorphenamine when taken concomitantly with phenytoin may cause a decrease in phenytoin elimination.

#### 9. FERTILITY PREGNANCY AND LACTATION

The product should not be used in pregnancy and lactation, unless the anticipated benefits outweigh their potential risk, do not exceed the recommend dose.

#### 10. CLINICAL PHARMACOLOGY

**Dextromethorphan Hydrobromide:** Dextromethorphan hydro bromide monohydrate is a salt of the methyl ether dextrorotatory isomer of levorphanol a narcotic analgesic. The duration of action after oral administration is approximately 3 to 8 hours for dextromethorphan hydro bromide.

**Pseudoephedrine hydrochloride:** Pseudoephedrine is a sympathomimetic amine commonly used as a decongestant. It causes decrease in the symptoms of nasal congestion by acting on the adrenergic receptors. These adrenergic receptors are located on the muscles lining the walls of blood vessels. Pseudoephedrine causes vasoconstriction which allows less fluid to leave the blood vessels and enter the sinus linings.

**Chlorpheniramine maleate:** Chlorpheniramine maleate is absorbed relatively slowly from the gastrointestinal tract. It is widely distributed in the body and enters the CNS. It's more rapid and extensive absorption, faster clearance, and a shorter half-life has been reported in children compared to adults.

#### 11. OVERDOSAGE

Symptoms of overdose may include restlessness, drowsiness, tetany, hallucinations, excitement, ataxia, convulsions, fever, nausea, vomiting, difficulty in micturition, flushing, palpitations, tachycardia, dryness of mouth, blurred vision and cardiac arrhythmias. Overdose should be treated by general symptomatic and supportive means.

#### Presentation:

Cosome® Cough Syrup: Available in 120 ml glass bottle.

Store below 30°C.

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

Protect from light and heat.

روشنی اور گرمی سے محفوظ رکھیں۔

Keep all medicines out of the reach of children.

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

To be sold on the prescription of a registered

صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لئے۔

medical practitioner only.

Manufactured by:

**Martin Dow Marker Ltd**

7, Jail Road, Quetta, Pakistan.

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