

PRODUCT NAME	AMBRO PLUS (Ambroxol Hydrochloride, Dextromethorphan Hydrobromide, & Chlorpheniramine Maleate Syrup)
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HEALTH PROFESSIONAL INFORMATION

1.Trademark name/ Generic Name

AMBRO PLUS (Ambroxol Hydrochloride, Dextromethorphan Hydrobromide, & Chlorpheniramine Maleate Syrup)

2.Pharmaceutical form

Pink colour clear syrup.

3. Strength; Route of administration; Dosage form

Strength: Ambroxol HCL BP 20 mg

Dextromethorphan Hydrobromide BP 10 mg

Chlorpheniramine Maleate BP 2 mg

Route of administration: Oral

Dosage form: Oral Liquid

4. Dosage/ Dose

This syrup is indicated for adults and children above 2 years of age for symptomatic relief of cough and upper respiratory symptoms. It is not recommended for children under 2 years without medical advice.

Dosage Schedule:

Adults and Children (12 years of age and older): 1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls in 24 hours.

Children (6 to under 12 years of age): 1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonfuls in 24 hours.

Children 2 to under 6 years of age: 1/4 teaspoonful (1.25 mL) every 4 to 6 hours, not to exceed 1.5 teaspoonfuls in 24 hours.

Not recommended for use in children under 2 years of age.

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5. Indications; age indication

AMBRO PLUS Syrup is primarily used to treat cough (dry & Productive) Additionally, it is also used to treat allergic symptoms such as sneezing, running nose and throat irritation.

6. Use in special populations

The use of Ambroxol Hydrochloride, Dextromethorphan Hydrobromide, and Chlorpheniramine Maleate syrup in special populations requires medical consultation due to potential risks and the need for dose adjustments. The combination should be used with caution, especially in individuals with pre-existing conditions.

7. Method of use

For oral use.

8. Pharmacological information

Pharmacological Properties

Pharmacotherapeutic group: Mucolytic, Antitussives, Antihistamines

ATC code: Ambroxol Hydrochloride (R05CB06), Dextromethorphan Hydrobromide (R05DA09), Chlorpheniramine Maleate (R06AA04)

The syrup containing Ambroxol Hydrochloride, Dextromethorphan Hydrobromide, and Chlorpheniramine Maleate (CPM) provides relief through distinct pharmacodynamic actions and follows specific pharmacokinetic pathways.

Mechanism of Action and Pharmacodynamic Properties:

The pharmacodynamic properties describe how the drugs affect the body. Each ingredient targets a specific set of symptoms:

Ambroxol Hydrochloride: Functions as a mucolytic agent. It increases respiratory tract secretions and enhances the production of pulmonary surfactants, which decreases the viscosity and surface_tension of the mucus (phlegm). This facilitates mucociliary clearance, making it easier to cough out the loosened phlegm.

Dextromethorphan Hydrobromide: Acts as a cough suppressant or antitussive agent. It centrally acts on the cough centre in the medulla of the brain, blocking the nerve signals that trigger the urge to cough. This provides relief from persistent, dry, and irritating coughs.

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Chlorpheniramine Maleate (CPM): Is a first-generation antihistamine. It blocks histamine H1 receptors, thereby preventing histamine (a chemical released during allergic reactions) from binding to its receptors. This action alleviates allergy symptoms such as sneezing, runny nose, watery eyes, and itching.

Pharmacokinetic Properties

The pharmacokinetic properties describe how the body processes the drugs (absorption, distribution, metabolism, and excretion).

Absorption: All three components are rapidly and well absorbed after oral administration.

Ambroxol: Oral bioavailability is approximately 70-80%. Peak plasma concentration is reached within 1–2.5 hours.

Dextromethorphan: Rapidly absorbed from the gastrointestinal tract. Time to peak concentration (Tmax) is around 2.86 hours.

Chlorpheniramine Maleate (CPM): Readily absorbed from the GI tract, though with some first-pass metabolism.

Distribution: The drugs are distributed widely throughout body tissues.

Ambroxol: Shows pronounced distribution into body tissues, with the highest concentration observed in the lungs. It is approximately 90% protein bound. It also crosses the placental barrier and enters breast milk.

Dextromethorphan: Has a large volume of distribution and is 60-70% protein bound in the serum.

Metabolism:

Ambroxol: Undergoes significant first-pass metabolism, mainly in the liver via glucuronidation and cleavage to minor metabolites, including dibromanthranilic acid.

Dextromethorphan: Extensively metabolized in the liver, primarily by the CYP2D6, CYP3A4, and CYP2C9 enzyme systems, to its active metabolite dextrorphan (an NMDA receptor antagonist) and other metabolites.

Chlorpheniramine Maleate (CPM): Undergoes extensive metabolism in the liver.

Excretion: The drugs are primarily eliminated via the kidneys in the urine.

Ambroxol: Approximately 83% of the dose is excreted in the urine, with an elimination half-life of roughly 10 hours.

Dextromethorphan: Has an elimination half-life ranging from 3 to 30 hours, depending on individual metabolic rates (CYP2D6 phenotype).

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Chlorpheniramine Maleate (CPM): Excreted mainly in the urine.

Clinical efficacy and safety

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

9. Clinical Information

The syrup containing Ambroxol Hydrochloride, Dextromethorphan Hydrobromide, & Chlorpheniramine Maleate is primarily used to provide relief from symptoms of cough, cold, and allergies, including dry and productive coughs, runny nose, sneezing, and throat irritation.

10. Precautions; Warnings; Contraindication

Precaution:

General: Before prescribing medication to suppress or modify cough, identify and provide therapy for the underlying cause of the cough and take caution that modification of cough does not increase the risk of clinical or physiologic complications. Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus 1 and prostatic hypertrophy.

Information for Patients: Avoid alcohol and other CNS depressants while taking this product. Patients sensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive to sympathomimetic amines may notice mild CNS stimulation. Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery.

Warning:

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intraocular pressure or prostatic hypertrophy. Sympathomimetic amines may produce CNS stimulation with convulsions or cardiovascular collapse with accompanying hypotension. Administration of dextromethorphan may be accompanied by histamine release and should be used with caution in atopic children.

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Pregnancy & Lactation

Pregnancy

Limited data is available on the effect of Ambroxol + Chlorpheniramine Maleate + Dextromethorphan Hydrobromide in pregnancy. Hence, if you are pregnant or planning pregnancy, inform your doctor before taking this medicine. Your doctor may prescribe this medicine if the benefits outweigh the risks.

Breast-feeding

It is unknown whether Ambroxol + Chlorpheniramine Maleate + Dextromethorphan Hydrobromide is excreted in human milk. Hence, if you are a nursing mother, inform your doctor before taking this medicine. Your doctor may prescribe this medicine if the benefits outweigh the risks.

Effects on ability to drive and use machines

Ambroxol + Chlorpheniramine Maleate + Dextromethorphan Hydrobromide may cause dizziness or drowsiness in some people. Avoid driving or using any machine, if you experience such side effects after taking this medicine.

Liver & Kidney:

Ambroxol + Chlorpheniramine Maleate + Dextromethorphan Hydrobromide should be used with caution in liver & kidney conditions. Inform your doctor if you have liver impairment. Your doctor may adjust the dose if necessary based on your condition.

Contraindication:

Patients with hypersensitivity or allergic to any of its ingredients. Sympathomimetic amines are contraindicated in patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy. Antihistamines are contraindicated in patients with narrow angle glaucoma, urinary retention, peptic ulcer and during an asthma attack.

Dextromethorphan should not be used in patients receiving a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug.

11. Interactions

Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of

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antihistamines. Sympathomimetic amines may reduce the antihypertensive effects of reserpine, veratrum alkaloids, methyl dopa and mecamylamines. Effects of sympathomimetics are increased with MAO inhibitors and beta-adrenergic blockers. Dextromethorphan is contraindicated with monoamine oxidase inhibitors (MAOI).

12. Overdose

Symptoms of Ambro Plus overdose can lead to severe drowsiness, seizures, widened pupils, nausea, vomiting fast heart beat and hallucinations. Immediate medical attention is essential if these symptoms occur.

Management of Overdose

Activated Charcoal: to absorb the drug, gastric lavage (stomach pumping), and laxatives to help expel the drug.

Intravenous (IV) Fluids: to maintain hydration, breathing support and monitor the heart activity.

Psychiatric consultation is needed if overdose involves psychosis or suicidal behaviour.

13. Contents / volume

Each 5 ml Contains:

Ambroxol HCL BP 20 mg

Dextromethorphan HBR BP 10 mg

Chlorpheniramine Maleate BP 2 mg

Flavoured Syrup Base Q.S.

Colour: Ponceau 4R

14. Number of doses (for multi doses presentation)

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Route of Administration: For oral use.

15. Excipients statement

Pharma Grade Sugar BP, Sodium Citrate BP, Di Sodium EDTA BP, Citric Acid Monohydrate BP, Menthol BP, Potassium Sorbate BP, Ponceau 4R IH, Raspeberry Flavor IH Sorbitol Solution 70 %, (Non-crystallizing) BP, Sodium Benzoate BP, Glycerin BP, Sucralose BP.

16. Storage temperature

Keep in cool and dry place. Protect from direct sunlight. Store below 30° C.

17. Instructions for preparation if applicable

Not Applicable

18. Name and address of final product manufacturer

Rhombus Pharma Pvt. Ltd.

Survey No 807/002, Near

Ethrico Industries, Lakshmanpura, Ta: Kadi,

Dist: Mehsana 382165.

Gujarat. India

Marketing Authorisation Holder:

ELR Pharmaceuticals FZCO

Premises No: 22584-001, DSO-IFZA

DDP, Dubai Silicon Oasis.

Dubai. United Arab Emirates.

Date: 28.11.2025

Rivision No.: 03

19. Dispensing condition

Prescription Only Medication.