

Dulsana® Mild Cough syrup

COMPOSITION

Each teaspoonful (5 ml) contains:

Carbinoxamine maleate.....	1.000 mg
Ephedrine hydrochloride.....	1.800 mg
Ammonium chloride.....	50.000 mg
Sodium citrate.....	20.000 mg
Citric Acid.....	10.000 mg
Menthol.....	0.125 mg
FD&C Yellow # 6 (sunset yellow).....	0.0025 mg
Excipient q.s.....	5 ml

in a flavored syrup base.

ACTION

Dulsana® Mild syrup is an effective, safe and pleasant-tasting expectorant cough preparation for children.

Carbinoxamine maleate, an antihistamine, has local anesthetic and mild sedative properties.

Ephedrine hydrochloride is a decongestant and bronchodilator.

Ammonium chloride, Sodium citrate and Citric acid aid in loosening and liquefying the thick tenacious secretions which often accompany chest colds.

Menthol is cooling, soothing and has a mild local analgesic action.

INDICATIONS

Dulsana® Mild syrup is indicated as a mild expectorant in children for the relief of cough due to allergy, colds or other acute upper respiratory tract infections.

DOSAGE

Children 10-14 years: one or two teaspoonful (5-10 ml) three or four times daily.

6-9 years: one teaspoonful (5 ml) three or four times daily.

Do not use in children under 6 years of age.

CONTRAINDICATIONS

Ephedrine hydrochloride: Closed angle glaucoma, pheochromocytoma, asymmetric septal hypertrophy, concomitant or recent (previous 14 days) monoamine oxidase inhibitor (MAOI) therapy, general anaesthesia with halogenated hydrocarbons (particularly halothane), tachyarrhythmias or ventricular fibrillation, hypersensitivity to ephedrine or other stimulants.

Carbinoxamine: Severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy. Patients with narrow angle glaucoma, urinary retention, peptic ulcer and during an asthma attack. Patients with hypersensitivity to carbinoxamine.

CAUTIONS

A persistent cough may be a sign of a serious condition.

Ephedrine may cause urinary retention.

This preparation contains an antihistamine and may cause drowsiness.

Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus and prostatic hypertrophy.

Overdosage

Symptoms of Overdosage:

Should antihistamine effects predominate, central action constitutes the greatest danger. In the small child, predominant symptoms are excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils, coma and death may occur in severe cases. In the adult, fever and flushing are uncommon; excitement leading to convulsions and post-ictal depression is often preceded by drowsiness and coma. Respiration is usually not seriously depressed; blood pressure is usually stable. Should sympathomimetic symptoms predominate, central effects

include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability and insomnia. Cardiovascular and renal effects include difficulty in micturition, headache, flushing, palpitation, cardiac arrhythmia, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, metallic taste, anorexia, nausea, vomiting, diarrhea and abdominal cramps.

DRUG INTERACTIONS

Please inform your physician of any medications you are taking, including those available without a prescription.

Ephedrine: Should not be used in conjunction with certain antidepressants, namely SNRIs (serotonin-norepinephrine re-uptake inhibitors), as this increases the risk of the side effects due to excessive serum levels of norepinephrine.

α-Adrenergic blocking agents, Atropine, Diuretics.

Carbinoxamine: Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Sympathomimetic amines may reduce the antihypertensive effects of reserpine, veratrum alkaloids, methyldopa and mecamylamines. Effects of sympathomimetics are increased with MAO inhibitors and beta-adrenergic blockers.

PREGNANCY AND LACTATION

If you are pregnant or are a nursing mother, please consult with your physician prior to using this medication.

SIDE EFFECTS

Should any troublesome or unusual symptoms develop, a doctor should be consulted.

Ephedrine hydrochloride: With large doses of ephedrine patients will experience nervousness, insomnia, vertigo, headache, tachycardia, palpitation and sweating. Some patients have nausea, vomiting and anorexia. Vesical sphincter spasm may occur and result in difficult and painful urination. Urinary retention may develop in males with prostatism.

Carbinoxamine: Antihistamines may cause sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and rarely excitability in children. Urinary retention may occur in patients with prostatic hypertrophy. Sympathomimetic amines may cause convulsions, CNS stimulation, cardiac arrhythmia, respiratory difficulties, increased heart rate or blood pressure, hallucinations, tremors, nervousness, insomnia, pallor and dysuria.

STORAGE CONDITIONS

Do not store above 30°C.

Store in the original package.

Do not use after expiry date

PRESENTATION

Dulsana® Mild cough syrup is available in bottles of one hundred milliliters.

This is a medicament

-A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

-The doctor and the pharmacist are experts in medicine, its benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed.

-Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENT OUT OF REACH OF CHILDREN.

Manufactured in Zouk Mosbeh, Lebanon, by

ALGORITHM S.A.L.

®Registered Trademark

P1635-03

Rev. No. 09/2011