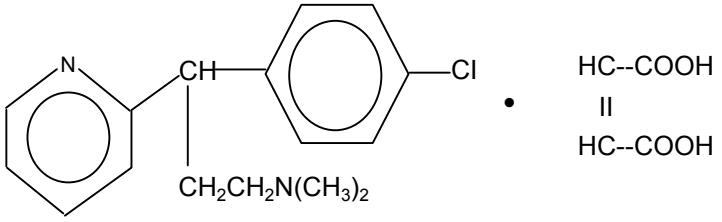
MESCOLOR® TABLETS

DESCRIPTION: Each scored, dye-free white MESCOLOR® Tablet contains:

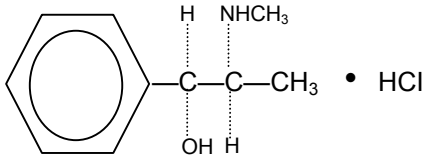
Chlorpheniramine Maleate	8 mg
Pseudoephedrine HCl	120 mg
Methscopolamine Nitrate	2.5 mg

in a specially-prepared base to provide a prolonged therapeutic effect. MESCOLOR® Tablets are intended for oral administration.

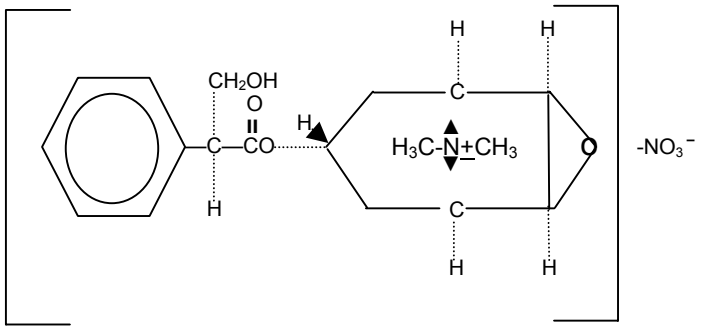
Chlorpheniramine Maleate is an antihistamine having the chemical name: 2-Pyridinepropanamine, Y-(4-chlorophenyl)-*N, N*-dimethyl-, (Z)-2-butenedioate (1:1), and has the following structural formula:



Pseudoephedrine HCl is a decongestant having the chemical name: Benzenemethanol, α -[1-(methylamino)ethyl]-, [*S-(R*,R*)*]-, hydrochloride, and has the following structural formula:



Methscopolamine Nitrate is an anticholinergic having the chemical name: 3-Oxa-9-azoniatricyclo [3.3.1.$0^{2,4}$] nonane, 7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9,9-dimethyl-, nitrate, [7(S)- (1α, 2ß, 4ß, 5α, 7ß)]-, and has the following structural formula:



Clinical Pharmacology: *Chlorpheniramine Maleate* is an alkylamine-type antihistamine, which possesses anticholinergic and sedative effects. Antihistamines competitively antagonize histamine at the H_1 receptor site. Thus, activation of H_1 receptors by released histamine is

prevented resulting in increased vascular permeability, increased mucus production. Pruritis and sneezing are reduced.

Pseudoephedrine Hydrochloride is an orally active sympathomimetic amine, which exerts a decongestant action on the nasal mucosa. It does this by vasoconstriction which results in a reduction of tissue hyperemia, edema, nasal congestion, and an increase in nasal airway patency. The vasoconstrictive action of pseudoephedrine is similar to that of ephedrine. In the usual dose it has minimal vasopressor effects. Pseudoephedrine is rapidly, and almost completely, absorbed from the gastro-intestinal tract. It has a plasma half-life of 6 to 8 hours. Acidic urine is associated with faster elimination of the drug. The drug is distributed to body tissues and fluids, including the fetal tissue, breast milk and the central nervous system (CNS). Approximately 50% to 75% of the administered dose is excreted unchanged in the urine; the remainder is apparently metabolized in the liver to inactive compounds by N-demethylation, parahydroxylation and oxidative deamination.

Methscopolamine Nitrate is a quaternary ammonium derivative of the anticholinergic scopolamine, which possesses the peripheral actions of the belladonna alkaloids, but does not exhibit the central actions because of its lack of ability to cross the bloodbrain barrier. Its antimuscarinic effect causes drying of mucous secretions.

INDICATIONS AND USAGE: MESCOLOR® Tablets are indicated for the temporary relief of symptoms of allergic rhinitis, vasomotor rhinitis, sinusitis and the common cold.

CONTRAINDICATIONS: Patients with hypersensitivity 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 and anticholinergics are contraindicated in patients with narrow-angle glaucoma, urinary retention, and peptic ulcer, during an asthma attack.

PRECAUTIONS:
General: Use with caution in patients with diabetes, hypertension, cardiovascular diseases and hypersensitivity to sympathomimetic amines. Antihistamines may cause drowsiness and ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.

Information to Patients: Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. Do not crush or chew MESCOLOR® Tablets prior to swallowing. The antihistamine in this product may have additive effects with alcohol and other central nervous system depressants (hypnotics, sedatives, tranquilizers).

Drug Interactions: Beta-adrenergic blockers and MAO inhibitors may potentiate the pressor effect of pseudoephedrine. Concurrent use of digitalis glycosides may increase the possibility of cardiac arrhythmias. Sympathomimetics may reduce the hypotensive effects of guanethidine, mecamylamine, methyldopa, reserpine and veratrum alkaloids. Concurrent use of tricyclic antidepressants may antagonize the effects of pseudoephedrine. Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbituates and other CNS depressants may have an additive effect.

Laboratory Test Interactions: Antihistamines may suppress the wheal and flare reactions to antigen skin testing. Considerable interindividual variation in the extent and duration of suppression have been reported; dependant on the antigen and test technique, antihistamine and dosage regimen, time since last dose and individual response to testing. In one study, usual oral dosages of chlorpheniramine suppressed the wheal response for about 2 days after the last dose. Whenever possible, antihistamines should be discontinued for about 4 days prior to skin testing since they may prevent otherwise positive reaction to dermal reactivity indicators.

Pregnancy: Category C: Animal reproduction studies have not been conducted with MESCOLOR®. It is also not known whether MESCOLOR® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MESCOLOR® should be given to a pregnant woman only if clearly needed.

Nursing Mothers: Pseudoephedrine is excreted in breast milk. Use of this product by nursing mothers is not recommended because of the higher than usual risk to infants from sympathomimetic amines.

Pediatric Use: Safety and effectiveness of MESCOLOR® in children below the age of 6 have not been established. May cause excitability in children.

Use in Elderly: The elderly (60 years and older) are more likely to have adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression and death.

ADVERSE REACTIONS: Sympathomimetic amines may cause tachycardia, palpitations, nervousness, insomnia, restlessness, headache, dizziness, gastric irritation, and irritability. Sympathomimetic amines have been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension. Urinary retention may occur in patients with prostatic hypertrophy. Antihistamines and anticholinergics may cause drowsiness, dizziness, blurred vision, and excessive drying of the nose, throat and mouth.

OVERDOSAGE: The treatment of overdosage should provide symptomatic and supportive care. Induction of emesis and gastric lavage may be performed if the patient is alert and seen within early hours after ingestion. Either isotonic or half-isotonic saline may be used for lavage. Administration of an activated charcoal slurry is beneficial after lavage and/or emesis if less than 4 hours have passed since ingestion. Stimulants should not be used because they may precipitate convulsions. Use of a short acting barbituate is recommended if convulsions or marked CNS excitement occur. Since the effects of MESCOLOR® may last up to 12 hours, the patient should be monitored for at least the length of time and treated as necessary. The LD_{50} of pseudoephedrine (single oral dose) has been reported to be 726 mg/kg in the mouse, 2206 mg/kg in the rat, and 1177 mg/kg in the rabbit. The toxic and lethal concentrations in human biologic fluids are not known. Urinary excretion increases with acidification and decreases with alkalinization of the urine. There are few published reports of toxicity due to pseudoephedrine and no case of fatal overdosage has been reported. In severe cases of overdosage, it is essential to monitor both the heart (by electrocardiograph) and plasma electrolytes, and to give intravenous potassium as indicated. Vasopressors may be used to treat hypotension. Excessive CNS stimulation may be counteracted with parenteral diazepam. Stimulants should not be used.

DOSAGE AND ADMINISTRATION: Adults and children 12 years of age and older: One tablet every 12 hours not to exceed 2 tablets in 24 hours. **Children 6-12 years:** One half (1/2) tablet every 12 hours not to exceed 1 tablet in 24 hours. **MESCOLOR® is not recommended for children under 6 years of age. Safety and effectiveness of MESCOLOR® in children below the age of 6 have not been established. May cause excitability in children.** Tablets may be broken in half for ease of administration without affecting release of medication but should not be crushed or chewed prior to swallowing.

HOW SUPPLIED: MESCOLOR® is available as a scored, dye-free, film-coated, white tablet imprinted with HP 15. Bottles of 100 (NDC 59630-150-10).

Store at controlled room temperature between 15°-30°C (59°-86°F). Dispense in tight, light-resistant containers (USP/NF).

Rx only

Manufactured for:
First Horizon Pharmaceutical Corp.
Roswell, GA 30076
Manufactured by:
Anabolic, Inc., Irvine, CA 92614