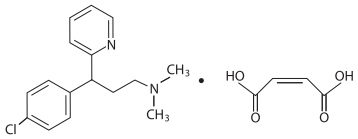
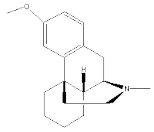
Extendryl® DM (chlorpheniramine maleate, dextromethorphan and methscopolamine nitrate)
Extended Release Tablet
Rx Only

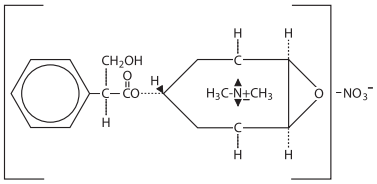
DESCRIPTION:
Each extended release tablet contains:
Chlorpheniramine Maleate…… 8 mg
Dextromethorphan……..30 mg
Methscopolamine Nitrate…… 2.5 mg
EXTRENDYL® DM is formulated in a special base to provide a prolonged therapeutic effect. This product contains ingredients of the following therapeutic classes: antihistamine, antitussive and anticholinergic.



Chlorpheniramine Maleate is an antihistamine having the chemical name 2-Pyridinepropanamine, γ-(4 chlorophenyl)-N,N-dimethyl, (Z)-2-butenedioate (1:1), having the structural formula above.



Dextromethorphan is an antitussive. Chemically, it is 3-methoxy-17-methyl-(9alpha,13alpha,14alpha)-morphinan, having the structural formula above:



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)]-, having the structural formula above:

CLINICAL PHARMACOLOGY:
Chlorpheniramine maleate is an alkylamine antihistamine which possesses anticholinergic and sedative effects. Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies. Dextromethorphan is an antitussive agent, which unlike the isomeric levorphanol, has no analgesic or addictive properties. The drug acts centrally and elevates the threshold for coughing. It is about equal to codeine in depressing the cough reflex. In therapeutic dosages, it does not inhibit ciliary activity. Dextromethorphan is rapidly absorbed from the gastrointestinal tract, metabolized by the liver and excreted primarily in the urine. Peak plasma concentrations are reached in approximately 2.5 hours and Dextromethorphan has a plasma half-life of three to four hours. Methscopolamine nitrate is a derivative of scopolamine, is an anticholinergic which possesses the peripheral actions of the belladonna alkaloids, but does not exhibit the central actions because of its inability to cross the blood-brain barrier.

INDICATIONS AND USAGE:
Extendryl® DM provides symptomatic relief of respiratory congestion, allergic rhinitis, vasomotor rhinitis, and respiratory conditions characterized by dry, nonproductive cough and in the presence of tenacious mucus plugs in the respiratory tract.

CONTRAINDICATIONS:
Extendryl® DM are contraindicated in individuals with a known hypersensitivity to any of its ingredients or in patients with glaucoma, hypertension, cardiac disease, or hyperthyroidism or those receiving MAO inhibitors and should not be administered in patients taking selective serotonin reuptake inhibitors and monoamine oxidase inhibitors.

WARNINGS:
Extendryl® DM may cause excitability especially in children. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages. Use caution when driving a motor vehicle or operating machinery.

PRECAUTIONS:
General: Persistent cough may indicate a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by a high fever, rash or persistent headache, consult a physician.

Information for Patients: Because this product may cause blurring of vision or drowsiness, patients should be cautioned against driving or operating machinery.

Drug Interactions: Dextromethorphan should not be taken with Monoamine Oxide Inhibitors (MAOIs) and Selective Serotonin Reuptake Inhibitors (SSRIs) because of an apparent serotonin syndrome (fever, hypertension, arrhythmias). Should be used with caution in atopic children due to histamine release. Additive CNS depressant effects when co-administered with alcohol, antihistamines, psychotropics, and other CNS depressant drugs. Although side effects from dextromethorphan are not common, they can occur. Side effects can include dizziness, lightheadedness, drowsiness, nervousness, restlessness, upset stomach, vomiting and stomach pain.

Pregnancy: Pregnancy Category C: It is not known whether the product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The product should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 6 have not been established.

Geriatric Use: Elderly people are particularly sensitive to drugs with anticholinergic effects because the amount of acetylcholine in the body decreases with age and because their bodies are less able to use what's there. Drugs that have anticholinergic effects can cause confusion, blurred vision, constipation, dry mouth, light-headedness, and difficulty with urination or loss of bladder control.

ADVERSE REACTIONS:
Side effects from Extendryl® DM include dry mouth, xerostomia, blurred vision, bradycardia, tachycardia, mydriasis, flushing, palpitation, dizziness, constipation, urinary retention, drowsiness, increased irritability or excitabilty, nausea or dysphagia, confusion and memory impairment. Gastrointestinal: Nausea, xerostomia, diarrhea, abdominal pain, appetite increase, weight gain Central Nervous System: Headache, excitability, fatigue, nervousness, dizziness Cardiovascular: Fast heartbeat. General: Use cautiously, if at all, in the presence of pyloric obstruction. Use with caution in those over 40 years of age, in the presence of diabetes mellitus or urinary retention, and in men with prostatic hypertrophy or a history of bladder difficulty. If disturbances in urination occur, medication should be discontinued for 1 or 2 days and then resumed at a lower dosage. Antihistamines may cause excitability, especially in children.

OVERDOSAGE:
Since the effects of Extendryl® DM may last up to 12 hours, treatment of overdosage directed towards supporting the patient and reversing the effects of the drug should be continued for at least that length of time.
Symptoms: Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures.

Treatment: Treatment of acute overdosage should be based upon treating the patient for the symptoms of overdosage. The treatment of overdosage should provide symptomatic and supportive care. If the amount ingested in considered dangerous or excessive, induce vomiting with ipecac syrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage using a large bore tube. If indicated, follow with activated charcoal and a saline cathartic. Naloxone HCl 0.005 mg/kg intravenously may be of value in reversing the CNS depression that may occur from an overdose of Dextromethorphan. CNS stimulants may counter CNS depression. Should CNS hyperactivity or convulsive seizures occur, intravenous short-acting barbiturates may be indicated. Hypertensive responses and/or tachycardia should be treated appropriately. Oxygen, intravenous fluids, and other supportive measures should be employed as indicated.

DRUG ABUSE AND DEPENDENCE:
Central nervous system stimulants have been abused. At high doses, subjects commonly experience an elevation of mood, a sense of increased energy and alertness, and decreased appetite. Some individuals become anxious, irritable, and loquacious. In addition to the marked euphoria, the user experiences a sense of markedly enhanced physical strength and mental capacity. With continued use, tolerance develops, the user increases the dose, and toxic signs and symptoms appear. Depression may follow rapid withdrawal.

DOSAGE AND ADMINISTRATION:
Adults and adolescents 12 years of age and older: 1 tablet twice daily not to exceed 2 tablets in 24 hours.
Children 6 to 12 years: ½ tablet every 12 hours, not to exceed 1 tablet in 24 hours.
Not recommended for children under 6 years of age.
Tablets may be broken in half for ease of administration.
Geriatric patients may be more sensitive to the effects of this medication. Adjust adult dose accordingly.
DO NOT CRUSH OR CHEW TABLETS PRIOR TO SWALLOWING.

HOW SUPPLIED:
Extendryl® DM is available in a dye-free, scored tablet embossed with AP bisect 202. Plain bottom. Bottles of 100. NDC 014629-202-01. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

STORAGE:
Store at controlled room temperature, 20°-25°C (68°-77°F).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

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Manufactured for:
Auriga Pharmaceuticals, LLC
An Auriga Laboratories Company
Norcross, GA 30092

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