

Extendryl[®]
JR

(phenylephrine hydrochloride /
chlorpheniramine maleate /
methscopolamine nitrate)
Extended Release Tablets

Rx Only

EJRPI-02 500216 Rev: 06/07

DESCRIPTION:

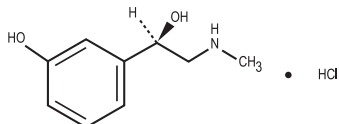
Each **Extendryl JR Extended Release Tablet** (capsule-shaped tablet) contains:

Phenylephrine
Hydrochloride 10 mg
Chlorpheniramine
Maleate 4 mg
Methscopolamine
Nitrate 1.25 mg

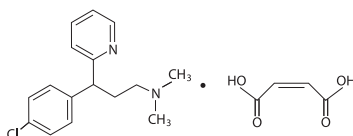
In a specially prepared base to provide a prolonged therapeutic effect.

Inactive ingredients include: calcium phosphate dibasic, magnesium stearate, methylcellulose, povidone and stearic acid.

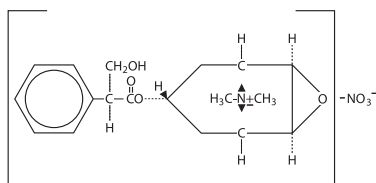
Phenylephrine Hydrochloride is a decongestant having the chemical name Benzene-methanol, 3-hydroxy- α -[(methylamino)methyl]-, hydrochloride (*R*)-, having the following structural formula:



Chlorpheniramine Maleate is an antihistamine having the chemical name 2-Pyridinepropanamine, γ -(4-chlorophenyl)-N,N-dimethyl-, (*Z*)-2-butenedioate (1:1), having 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*)-(1 α , 2 β , 4 β , 5 α , 7 β)]-, having the following structural formula:



Extendryl JR Tablets contain ingredients of the following therapeutic classes: nasal decongestant, antihistamine, and antisecretory agent.

CLINICAL PHARMACOLOGY:
Phenylephrine Hydrochloride is a sympathomimetic amine which acts predominantly on alpha receptors and has little action on beta receptors. It, therefore, functions as an oral nasal decongestant with minimal CNS stimulation.

Chlorpheniramine Maleate is an alkylamine type antihistamine. This group of antihistamines is among the most active histamine antagonists and is generally effective in relatively low doses. The drugs are not so prone to produce drowsiness and are among the most suitable agents for daytime use; but a significant proportion of patients do experience this effect.

Methscopolamine Nitrate is a quaternary ammonium derivative of 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 blood-brain barrier. In this formulation, it is used because of its antisecretory effects on the respiratory system.

INDICATIONS AND USAGE:

This product is indicated for the relief of upper respiratory symptoms due to seasonal and perennial allergic and non-allergic rhinitis, such as: nasal congestion, sinusitis, sneezing, lacrimation, vasomotor rhinitis, post-nasal drip, and hay fever.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease, patients on monoamine oxidase inhibitor (MAOI) therapy, patients with narrow angle glaucoma, urinary retention, peptic ulcer, and during an asthmatic attack.

WARNINGS:

Considerable caution should be exercised in patients with hypertension, diabetes mellitus, ischemic heart disease, hyperthyroidism, increased intraocular pressure, and prostatic hypertrophy. The elderly (60 years or older) are more likely to exhibit adverse reactions. Antihistamines may cause excitability, especially in children. At dosages higher than the recommended dose, nervousness, dizziness, or sleeplessness may occur. **Do not exceed recommended dosage.**

PRECAUTIONS:

General: Caution should be exercised in patients with high blood pressure, heart disease, diabetes, or thyroid disease. The antihistamines in this product may exhibit additive effects with other CNS depressants, including alcohol.

Information for Patients: Antihistamine may cause drowsiness, and ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.

Drug Interactions:

MAOIs and beta adrenergic blockers increase the effects of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyl-dopa, mecamylamine, reserpine and veratrum alkaloids. Concomitant use of antihistamines with alcohol and other CNS depressants may have an additive effect.



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

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Extendryl JR Tablets are administered to a nursing mother.

Pediatric Use: Safety and effectiveness in pediatric patients under 6 years of age have not been established. Use of antihistamines is not recommended in newborn or premature infants because this age group has an increased susceptibility to anticholinergic side effects, such as CNS excitation, and an increased tendency toward convulsion. In infants and children, overdosage may cause hallucinations, convulsions, and death. A paradoxical reaction characterized by hyperexcitability may occur in older children taking antihistamines. Use is not recommended for children under six (6) years of

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age. Infants and young children are especially susceptible to the toxic effects of anticholinergics. Close supervision is recommended for infants and children with spastic paralysis or brain damage since an increased response to anticholinergics has been reported in these patients, and dosage adjustments are often required. When anticholinergics are given to children where the environmental temperature is high, there is a risk of a rapid increase in body temperature because of the suppression of sweat gland activity. A paradoxical reaction characterized by hyperexcitability may occur in children taking large doses of anticholinergics. Appropriate studies with phenylephrine have not been performed in the pediatric population; however, no pediatric-specific problems have been documented to date.

Geriatric Use: Confusion, hallucinations, seizures, and CNS depression may be more likely to occur in geriatric patients taking sympathomimetic amines. Geriatric patients also may be more sensitive to the effects, especially the vasopressor effects, of sympathomimetic amines. Confusion, dizziness, sedation, hypotension, hyperexcitability, and anticholinergic side effects, such as dryness of mouth and urinary retention (especially in males), may be more likely to occur in geriatric patients taking antihistamines. Geriatric patients may respond to usual doses of anticholinergics with excitement, agitation, drowsiness, or confusion. Geriatric patients are especially susceptible to the anticholinergic side effects, such as constipation, dryness of mouth, and urinary retention (especially in males). If these side effects occur and continue or are severe, medication should probably be discontinued. Caution is also recommended when anticholinergics are given to geriatric patients, because of the danger of precipitating undiagnosed glaucoma. Memory may become severely impaired in geriatric patients, especially those who already have memory problems, with the continued use of anticholinergics, since these drugs block the action of acetylcholine, which is responsible for many functions of the brain, including memory function.

ADVERSE REACTIONS:

Adverse reactions include drowsiness, lassitude, nausea, giddiness, dryness of mouth, blurred vision, cardiac palpitations, flushing, increased irritability or excitement (especially in children).

OVERDOSAGE:

In all cases of suspected overdose, immediately call your regional poison control center, and/or contact a physician immediately. The stomach should be emptied promptly by lavage or by induction of emesis with Syrup of Ipecac. The installation of activated charcoal into the stomach also should be considered. The treatment of overdose is essentially symptomatic and supportive. If respiratory depression is present, treat promptly with oxygen and/or mechanical support of ventilation. If convulsions or marked CNS excitement occurs, only short-acting benzodiazepine-type drugs should be used.

DOSAGE AND ADMINISTRATION:

Extendryl JR Tablets: Adults and children 12 years of age and older: 1 to 2 tablets every 12 hours. Not to exceed 4 tablets daily. **Children 6 to under 12 years:** 1 tablet every 12 hours. Not to exceed 2 doses in 24 hours.

Not recommended for children under 6 years of age. Tablets should not be crushed or chewed prior to swallowing.

HOW SUPPLIED:

Extendryl JR Tablets are white, bisected, capsule shaped tablets with "AP" debossed on one end and "102" on the other. Available in bottles of 100 tablets (NDC 14629-102-01).

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°- 86°F). See USP Controlled Room Temperature. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

KEEP THIS AND ALL MEDICATION 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

Auriga Pharmaceuticals, LLC
An Auriga Laboratories
Company
Norcross, GA 30092

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