

Extendryl® PSE (pseudoephedrine hydrochloride and methscopolamine nitrate)

Extended Release Tablet

Patent Pending

Rx Only

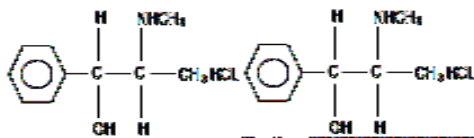
DESCRIPTION:

Each extended release tablet contains:

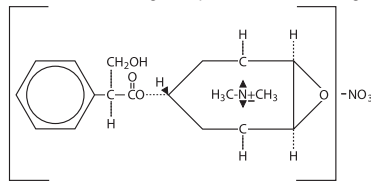
Pseudoephedrine Hydrochloride.....120 mg

Methscopolamine Nitrate.....2.5 mg

EXTENDRYL PSE is formulated in a special base to provide a prolonged therapeutic effect. This product contains ingredients of the following therapeutic classes: decongestant and anticholinergic.



Pseudoephedrine hydrochloride is an adrenergic (vasoconstrictor) agent with the chemical name (1S,2S)-2-methylamino-1-phenylpropan-1-ol hydrochloride. The molecular weight is 201.70. The molecular formula is $C_{10}H_{15}NO.HCl$.



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 structural formula above:

CLINICAL PHARMACOLOGY:

Pseudoephedrine hydrochloride is an orally active sympathomimetic amine and exerts a decongestant action on the nasal mucosa. Pseudoephedrine hydrochloride is recognized as an effective agent for the relief of nasal congestion due to allergic rhinitis. Pseudoephedrine produces peripheral effects similar to those of ephedrine and central effects similar to, but less intense than, amphetamines. It has the potential for excitatory side effects. Methscopolamine nitrate (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:

For temporary relief of nasal congestion associated with respiratory tract infections and related conditions such as sinusitis, pharyngitis, bronchitis, and asthma, when these conditions are complicated by tenacious mucus and/or mucus plugs and congestion.

CONTRAINDICATIONS:

EXTENDRYL PSE is contraindicated in patients with narrow-angle glaucoma or urinary retention, and in patients receiving monoamine oxidase (MAO) inhibitor therapy or within fourteen (14) days of stopping such treatment (see **PRECAUTIONS, Drug Interactions** section). It is also contraindicated in patients with severe hypertension, or severe coronary artery disease, and in those who have shown hypersensitivity or idiosyncrasy to its components, to adrenergic agents, or to other drugs of similar chemical structures. Manifestations of patient idiosyncrasy to adrenergic agents include insomnia, dizziness, weakness, tremor, or arrhythmias.

WARNINGS:

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or prostatic hypertrophy (see **CONTRAINDICATIONS**). Sympathomimetic amines may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension. The elderly are more likely to have adverse reactions to sympathomimetic amines.

PRECAUTIONS:

General: Methscopolamine increases the risk of heat stroke because it causes decreased sweating. Caffeine-containing beverages (coffee, tea, and cola) may increase the restlessness and insomnia caused by pseudoephedrine in sensitive individuals.

Information for Patients:

Drug Interactions: About 55-75% of an administered dose of pseudoephedrine hydrochloride is excreted unchanged in the urine; the remainder is apparently metabolized in the liver. Therefore, pseudoephedrine may accumulate in patients with renal insufficiency. Hypertensive crisis can occur with concurrent use of Pseudoephedrine HCl and monoamine oxidase (MAO) inhibitors, indomethacin, or with beta-blockers and methyl dopa. If a hypertensive crisis occurs, these drugs should be discontinued immediately and therapy to lower blood pressure should be instituted. Fever should be managed by means of external cooling.

Pregnancy: Pregnancy Category C:

Nursing Mothers: Because pseudoephedrine is excreted in milk, use of Extendryl® PSE in nursing mothers is not recommended.

Geriatric Use: The pharmacokinetics of pseudoephedrine has not been adequately studied in geriatric subjects.

ADVERSE REACTIONS:

Pseudoephedrine hydrochloride may cause mild CNS stimulation in hypersensitive patients. Nervousness, excitability, restlessness, dizziness, weakness, or insomnia may occur. Headache, nausea, drowsiness, tachycardia, palpitation, pressor activity, and cardiac arrhythmias have been reported. Sympathomimetic drugs have also been associated with other untoward effects such as fear, anxiety, tenseness, tremor, hallucinations, seizures, pallor, respiratory difficulty, dysuria, and cardiovascular collapse.

OVERDOSAGE:

Since this product contains two pharmacologically different components, treatment of overdose should be based upon the symptoms of the patients as it relates to the individual ingredients. Treatment of acute overdose would probably be based upon treating the patient for Pseudoephedrine Hydrochloride toxicity, which may manifest itself as excessive CNS stimulation resulting in excitement, tremor, restlessness, and insomnia. Other effect may include tachycardia, hypertension, pallor mydriasis, hyperglycemia and urinary retention. No organ damage or significant metabolic derangement is associated with Pseudoephedrine HCl overdose.

Symptoms: In large doses, sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, muscular weakness and tenseness, anxiety, restlessness, and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma and respiratory failure.

Treatment: Since the action of an extended release product may continue for as long as 12 hours, treatment of overdose should be directed toward reducing further absorption and supporting the patient for at least that length of time. Gastric emptying (syrup of ipecac) and/or lavage is recommended as soon as possible after ingestion, even if the patient has vomited spontaneously. 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 four hours have passed since ingestion. Saline cathartics, such as Milk of Magnesia, are useful for hastening the evacuation of unreleased medication.

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® PSE is available as a scored tablet debossed with AP bisect 201. Plain bottom. Bottles of 100. NDC 014629-201-01. 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.

Rx Only



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