PULMADRIN EXPECTORANT

Syrup

Composition

Each teaspoonful (5 ml) contains:

Guaifenesin	100 mg
Pseudoephedrine hydrochloride	30 mg
Triprolidine hydrochloride	1.25 mg

Action

Pulmadrin Expectorant facilitates the removal of mucus from the respiratory tract to provide symptomatic relief of cough, which becomes more productive. It contains three active components- an expectorant, a decongestant and an antihistamine.

Guaifenesin is a clinically established expectorant in bronchitic conditions. By increasing respiratory tract fluid, Guaifenesin reduces the viscosity of tenacious, clinging secretions. Cough frequency and intensity are thereby diminished in patients with non-productive cough.

Pseudoephedrine produces vasoconstriction, acting on alpha-adrenergic receptors in the mucosa of the respiratory tract. This action shrinks swollen nasal mucous membranes, thus reducing nasal congestion and thereby improving passage through the nasal airways. Sinus secretion is increased and the opening of obstructed eustachian tubes is facilitated.

Triprolidine is a powerful antihistamine for the control of allergic manifestations associated with upper respiratory tract infections.

Pseudoephedrine and Triprolidine are complementary. The mild, stimulating effect of pseudo-ephedrine reduces the drowsiness associated with the antihistamine component.

Indications

Pulmadrin Expectorant provides symptomatic relief of cough, where expectorant and upper respiratory tract decongestants are required.

Contraindications

- Known hypersensitivity to any of the components of the preparation or to other drugs of similar chemical structure.
- Concomitant treatment with monoamine oxidase inhibitors, or within 14 days of their discontinuation.
- Severe hypertension or severe coronary artery disease.
- Breastfeeding.

Newborn and Premature Infants

This preparation should not be used in newborn or premature babies, because of their greater susceptibility to the antimuscarinic effects of the antihistamine component, such as CNS excitation and an increased tendency toward convulsions.

Lower Respiratory Tract Conditions

Antihistamine-containing preparations should not be used to treat asthma or other lower respiratory tract conditions.

Other Medical Conditions

This preparation is contraindicated in patients with narrow-angle glaucoma, stenosing peptic ulcer, epilepsy, symptomatic prostatic hypertrophy, bladder neck obstruction and pyloroduodenal obstruction.

Warnings

Pregnancy
Category C
Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing Mothers
This preparation is associated with increased risk of undesirable side effects in infants and is therefore contraindicated in nursing mothers.

Paediatric Use
Use of antihistamines is not recommended in newborn or premature infants.
Antihistamine-containing preparations may diminish mental alertness; conversely, a paradoxical reaction characterized by hyperexcitability may occur.

Antihistamine over dosage, particularly in infants and children, may produce hallucinations, central nervous system depression, convulsions and even death.
Very young children may be more sensitive to the effects, especially the vasopressor effects, of sympathomimetic amines.

Elderly Use
Dizziness, sedation, hypotension, hyperexcitability, confusion and antimuscarinic side effects such as dryness of the mouth and urinary retention (especially in males), are more likely to occur in geriatric patients taking antihistamines. If the antimuscarinic side effects occur and continue or are severe, treatment should be discontinued.

Hallucinations, seizures, CNS depression and confusion may be more likely to occur in geriatric patients taking sympathomimetics. Geriatric patients may also be more sensitive to the effects, especially to the vasopressor effects, of sympathomimetic amines.

Patients above 60 years of age should therefore be closely monitored.

Adverse Reactions

Central Nervous System
Sedation, sleepiness, extrapyramidal reactions, dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paraesthesias, neuritis, convulsions, euphoria, hallucinations, hysteria and faintness.

Special Senses
Acute labyrinthitis, blurred vision, diplopia, vertigo and tinnitus.

Allergic
Peripheral, angioneurotic and laryngeal edema, drug rash, urticaria, photosensitivity and anaphylactic shock.

Gastrointestinal
Epigastric distress, dryness of mouth, anorexia, nausea, vomiting, diarrhea and constipation.

Cardiovascular
Hypotension, headache, palpitations, tachycardia and extrasystoles.

Genitourinary
Urinary frequency, difficult urination, urinary retention and early menses.

Respiratory
Tightness of chest and wheezing, nasal stuffiness and dryness of nose and throat.

Hematological
Hemolytic anemia, thrombocytopenia, leukopenia and agranulocytosis.

General
Fatigue, chills, headache and excessive perspiration.

Precautions

This preparation may cause drowsiness. Patients should be warned that their ability to perform potentially hazardous tasks requiring mental alertness or physical coordination, such as driving a vehicle or operating machinery, might be impaired. Similarly, children should be warned not to participate in activities such as riding a bicycle or playing near traffic.

Preparations containing antihistamines have an atropine like action. Therefore, they should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension.
Since antihistamines may cause epigastric distress, this preparation should preferably be taken after meals to diminish gastric irritation.

This preparation should be administered with caution in patients with mild to moderate hypertension, cardiovascular disease (including ischemic heart disease), diabetes mellitus, elevated intraocular pressure, hyperthyroidism, or prostatic enlargement.
Sympathomimetic amines may cause confusion, hallucinations or CNS stimulation in geriatric patients.

Drug Interactions

Triprolidine/ Alcohol/ CNS Depressants/ Tricyclic Antidepressants
Concurrent use may potentiate the CNS depressant effects of Triprolidine, or these agents.

Triprolidine/ Monoamine Oxidase Inhibitors
Concurrent use may prolong and intensify the antimuscarinic effects and CNS depressant effects of Triprolidine. Because of the Pseudoephedrine component, concurrent use is contraindicated.

Triprolidine/ Ototoxic Medications
Symptoms of ototoxicity may be masked if Triprolidine is used concurrently with ototoxic drugs, particularly aminoglycoside antibiotics such as amikacin, dihydrostreptomycin, gentamicin, kanamycin, neomycin, streptomycin, tobramycin and viomycin.

Pseudoephedrine/ Monoamine Oxidase Inhibitors
Concomitant treatment with monoamine oxidase inhibitors, or within 14 days of their discontinuation, is contraindicated.

Concurrent use may prolong and intensify cardiac stimulant and vasopressor effects (including headache, cardiac arrhythmias, and vomiting, sudden and severe hypertensive and hyperpyretic crises) because of release of catecholamines, which accumulate in intraneuronal storage sites during monoamine oxidase inhibitor therapy.

Pseudoephedrine/ ß-Adrenergic Blocking Agents
Concomitant use may result in unopposed alpha-adrenergic activity of Pseudoephedrine with a risk of hypertension, excessive bradycardia and possible heart block. The therapeutic effect of the ß-adrenergic blocking agents may be inhibited.

Pseudoephedrine/ Antihypertensive Drugs
Concomitant use may cause a reduced antihypertensive effect.

Pseudoephedrine/ Digitalis Glycosides/ Anesthetics (hydrocarbon inhalation)

Cardiac arrhythmias may occur when Pseudoephedrine is used prior to anesthesia or concurrently with digitalis glycosides, because of sensitization of the myocardium to the effects of Pseudoephedrine.

Pseudoephedrine/ Other Sympathomimetics
In addition to possibly increasing CNS stimulation, concurrent use may increase the effects of either the other sympathomimetics or Pseudoephedrine and the potential for side effects.

Diagnostic Interference
Antihistamine-containing preparations should be discontinued about 4 days prior to skin testing procedures, since they may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Dosage and Administration
This medication should be taken with water or food.
It is not to be used in children under 1 year of age.

Children
1-6 years: 1/2 teaspoonful every 6-8 hours.
6-12 years: 1 teaspoonful every 6-8 hours.

Children over 12 Years of Age and Adults
2 teaspoonfuls every 6-8 hours.

Over Dosage
Manifestations
The typical symptoms which may be observed following an overdose with an antihistamine-decongestant preparation include clumsiness or unsteadiness, severe dryness of the mouth, nose or throat, flushing or redness of the face, shortness of breath or troubled breathing (antimuscarinic effects, especially in children), convulsions, hallucinations (CNS stimulation, especially in children), severe drowsiness, continuing headache, unusually slow or fast heartbeat (sympathomimetic effects may indicate hypertension).

Treatment
General symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

In conscious patients, vomiting should be induced even though it may have occurred spontaneously. Adequate precautions must be taken to protect against aspiration, especially in infants and children. If vomiting cannot be induced, gastric lavage is indicated, using isotonic saline. Because Pseudoephedrine is rapidly absorbed from the gut, these measures should be instituted within 4 hours of the overdose in order to be effective.

Charcoal slurry or another suitable agent should be instilled into the stomach after vomiting or lavage. Saline cathartics or milk of magnesia may be of additional benefit.

In unconscious patients, the airway should be secured with a cuffed endotracheal tube before attempting to evacuate the gastric contents. Intensive supportive and nursing care is indicated, as for any comatose patient.
Do not administer CNS stimulants.

Hypotension is an early sign of impending cardiovascular collapse. If a vasopressor agent is needed, noradrenaline or phenylephrine should be used. Adrenaline should not be used since it may lower blood pressure further. lce packs and cooling sponge baths can aid in reducing the fever commonly observed in children.
Intravenous diazepam may be administered for delirium or convulsions.

Presentation
Bottle of 120 ml.