

PEACEF SYRUP

Peacef Syrup contains the antihistamine triprolidine hydrochloride, and the potent decongestant pseudoephedrine hydrochloride. Peacef Syrup provides prompt relief of nasal congestion due to cold and allergy.

Ingredient(s)

Each 5ml contains:

Pseudoephedrine HCl 30mg
Triprolidine HCl 1.25mg

Preservative:

Sodium Benzoate 25mg(0.5%)

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):

1. Triprolidine is a competitive histamine H1-receptor antagonist. In the guinea pig ileum, triprolidine is twice as active as chlorpheniramine. Triprolidine is five times more active than mepyramine in protecting against histamine induced bronchospasm.
2. Being an alkylamine H1-receptor antagonist, triprolidine has less anticholinergic and sedative activity than the phenothiazines.
3. Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has agonist activity at both β_1 and β_2 -adrenoreceptors, leading to increased cardiac output and to relaxation of bronchial smooth muscle. Its action on α -adrenoreceptors in the mucosa of the respiratory tract produces a degree of vasoconstriction which leads to a reduction in mucosal edema.
4. Triprolidine is promptly absorbed and rapidly reaches a therapeutic level. After oral administration, peak plasma concentrations are attained after 1.9 ± 0.6 hours. It is widely distributed throughout the body with an apparent volume of distribution of 8.7 ± 7.8 L/kg. Triprolidine is highly (90%) bound to plasma proteins; its mean half life is 3.0 hours.
5. Pseudoephedrine is rapidly and completely absorbed from the gastrointestinal tract following oral administration, with no presystemic metabolism. It achieves peak plasma concentration between 1 to 3 hours. It is eliminated largely unchanged in the urine (55~90%) in 24 hours, and has plasma half life of 5~8 hours.

Indication(s):

Symptomatic relief of sneezing, stuffy nose, and rhinorrhea caused by seasonal, allergic and vasomotor rhinitis.

Dosage and Administration:

Adults and children 12 years of age and over:- 10mL three times daily. Children under 12 years:-

6-12 years: 5mL three times daily.

2-5 years: 2.5mL three times daily.

Children less than 2 years of age should not receive Peacef Syrup unless directed by a physician.

Contraindication(s):

1. Patients with cardiovascular disease and endocrine disorder should avoid this medication.
2. Should not be administered to patients receiving MAO inhibitors or who have taken them within preceding 2 weeks.
3. Known hypersensitivity to this preparation.

Precautions / Warnings:

1. Peacef Syrup should be used with considerable caution in patients with narrow angle glaucoma, pyloroduodenal obstruction, prostatic hypertrophy, diabetes, ischemic heart disease, and hyperthyroidism.

2. It should be prescribed with caution in patients with severe impairment of renal and hepatic function.
3. In common with many other antihistamines, triprolidine may cause drowsiness and somnolence. Avoid alcoholic beverages and driving a motor vehicle or operating heavy machinery while taking this product.
4. Safe use of this product during pregnancy and lactation has not been established. It should be given to women who suspect pregnancy or to pregnant women and nursing mothers only when clearly needed.
5. Peacef Syrup may cause excitability especially in children. It should be used with caution in children under 6 years.
6. Not suitable for administration in children < 2 years.
7. Use with caution and according to doctor/pharmacist advice for children between 2 - 6 years.

Add in additional information as requested by BPFk.

Drug Interaction:

1. Concurrent use of Pseudoephedrine with Monoamine Oxidase (MAO) inhibitors can result rapid rise in blood pressure.
2. Other narcotic analgesic, alcohol, general anesthetics, tranquilizers, sedative hypnotics, surgical skeletal muscle relaxant, or other CNS depressant, by causing increased CNS depression.
3. Sympathomimetics may reduce the antihypertensive effects of methyldopa, guanethidine, reserpine and veratrum alkaloids.

Side Effects / Adverse Reactions:

The most frequent adverse reactions are dryness of mouth, nose and throat, sedation, sleepiness, dizziness and disturbed coordination. Other side effects such as hypotension, headache, palpitation, tachycardia, epigastric distress, anorexia, nausea, vomiting and thickening of bronchial secretion have also been reported.

Symptoms and Treatment for Overdosage and Antidotes:

Symptoms of acute toxicity of triprolidine include drowsiness, dizziness, incoordination, weakness, convulsion and respiratory depression. The main clinical features of Pseudoephedrine overdosage are similar to those of ephedrine poisoning with central nervous system stimulation leading to excitement, restlessness, rapid speech, hallucinations, hypertonicity and hyperreflexia, dilated pupil and tachycardia. In severe poisoning the tachycardia may lead to cardiac arrhythmias which may be further potentiated by the development of hypokalemia.

There is no specific treatment for the CNS effects. Necessary measures should be taken to maintain and support respiration. Gastric lavage should be performed if indicated and convulsion controlled with diazepam. β -blockers may be administered to control the tachycardia, arrhythmia and hypokalemia. Potassium supplements may also be required.

Storage Condition(s):

Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Shelf-life:

3 years from the date of manufacture.

Product Description and Packing(s):

A clear, slight orange solution.

Plastic bottle of 60ml, 100ml and 4L.

Manufacturer : **Y.S.P. INDUSTRIES (M) SDN. BHD.**

Factory : Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan, Malaysia.



Y. S. P.

Office : No. 18, Jalan Wan Kadir, Taman Tun Dr. Ismail,
60000 Kuala Lumpur, Malaysia.

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