PEACE® DM SYRUP

Ingredient(s):
Each 5ml contains:
Triprolidine Hydrochloride 1.25mg
Pseudoephedrine Hydrochloride 30mg
Dextromethorphan Hydrobromide 15mg
Sodium Benzoate (as preservative) 5mg

Pharmacology: (Summary of Pharmacodynamics and Pharmacokinetics):
Pharmacodynamics

1. Triprolidine provides symptomatic relief in conditions believed to depend wholly or partially upon the triggered release of histamine. It is a potent competitive histamine H_1-receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness.
2. Pseudoephedrine has a direct and indirect sympathomimetic activity and is an effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.
3. Dextromethorphan has an antitussive action. It controls coughs by depressing the medullary cough centre.
4. After oral administration of a single dose of 2.5mg triprolidine to adults, the onset of action as determined by the ability to antagonise histamine-induced weals and flares in the skin is within 1 to 2 hours. Peak effects occur at about 3 hours and, although activity declines thereafter, significant inhibition of histamine-induced weals and flares still occurs 8 hours after the dose.
5. Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for at least 4 hours.
6. A single oral dose of 10 – 20mg dextromethorphan produces its antitussive action within 1 hour and lasts for at least 4 hours.

Pharmacokinetics
After the administration of 2.5mg of triprolidine hydrochloride and 60mg of pseudoephedrine hydrochloride, the peak plasma concentration (Cmax) of triprolidine is approximately 5.5ng/ml – 6.0ng/ml occurring at about 1.5-2.0 hours (Tmax) after drug administration. Its plasma half life is approximately 3.2 hours. The Cmax of pseudoephedrine is approximately 180ng/ml with Tmax approximately 1.5-2.0 hours after drug administration. The plasma half-life is approximate 5.5hours (urine pH maintained between 5.0-7.0). The plasma half-life of pseudoephedrine is markedly decreased by acidification of urine and increased by alkalinisation.
Genetically controlled O-demethylation is the main determinant of dextromethorphan pharmacokinetics in human. It appears that there are two distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects.

Indication(s):
Relief of dry irritating cough associated with common cold, upper respiratory tract infections and allergic rhinitis. Helps dry up running nose and opens congested bronchi to aid clear breathing.

Dosage and Administration:
Adult and children > 12 years : 10 ml
6-12 years : 5ml
2 – 5 years: 2.5ml
To be taken three times daily
Orally administration. To be taken with or without food.

Contraindication(s):

1. Severe HTN (high blood pressure) or coronary artery disease.
2. Patient taking monoamine oxidase inhibitors (MAOIs) or within 2 weeks from stopping such treatment.

3. Concomitant administration of furazolidone.
4. Cough associated with asthma or excessive secretions.
5. Patients at risk of developing respiratory failure.

Precaution(s) / Warning(s):
1. Not to be used in children less than 2 years of age.
2. To be used with caution and doctor's advice in children 2 to 6 years of age.
3. Avoid alcohol, driving or operating machinery. Epilepsy, prostatic hypertrophy, glaucoma, hepatic disease, HTN, heart disease, diabetes, hyperthyroidism, stenosing peptic ulcer, pylori-duodenal obstruction, bladder neck obstruction. Pregnancy.

Interaction with Other Medicaments
1. Concomitant use of this product with sympathomimetic agents such as decongestants, tricyclic antidepressant, appetite suppressants and amphetamine-like psychostimulants or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.
2. Because of its pseudoephedrine content, this product may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, betanidine, guanethidine, debrisoquine, methyldopa, alpha-and beta-adrenergic blocking agents.

Pregnancy and Lactation
Caution should be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing foetus. Pseudoephedrine and triprolidine are excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known.

Side Effect(s) / Adverse Reaction(s):
Drowsiness, dizziness, constipation, GI discomfort.
Less common: Transient HTN, dry mouth, insomnia, restlessness, palpitation, allergic reactions eg. rash, tightness of chest, thickening of bronchial secretion, toxic psychosis & blood dyscrasias.

Symptoms and Treatment for Overdosage, and Antidote(s):
The sign of acute toxicity from this product may occur, drowsiness, lethargy, dizziness, ataxia, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, tachycardia, hypertension, hyperpyrexia, hyperactivity, irritability, convulsions, difficulty with micturition, nausea and vomiting.
Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage may be undertaken if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.
Naloxone has been used successfully as a specific antagonist to dextromethorphan toxicity in children.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Shelf-Life:
2 years from the date of manufacture.

Product Description and Packing(s):
Red color clear solution. Blackcurrant with menthol flavour.
Plastic bottle of 60ml, 100ml and 120ml.

Y. S. P.®
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