PAEDICOF SYRUP

Each 5ml contains: -

Dexchlorpheniramine maleate	1 mg
Pseudoephedrine HCl	15 mg
Dextromethorphan HBr	5 mg

Pharmacology:
Dextromethorphan HBr is a non-narcotic antitussive with effectiveness equal to codeine. It acts in the medulla oblongata to elevate the cough threshold. Dextromethorphan does not produce analgesia or induce tolerance, and has no potential for addiction. At usual doses, it will not depress respiration or inhibit cilliary activity. It is rapidly metabolised with trace amounts of parent compound in blood and urine. After administration of Dextromethorphan HBr 30mg by mouth to 6 subjects, the average plasma concentration of its major metabolites dextrophan and conjugates were about 21ng/ml after 15 min, about 107ng/ml after 30 min and about 368ng/ml after 60 min, with peak of about 381ng/ml after 2 hours.
Dexchlorpheniramine Maleate is an anti-histamine with anti-cholinergic properties. It is capable of producing a slight to moderate sedative effect. It appears to compete with histamine for receptor sites on effector cells and are of value clinically in the prevention and relief of many allergic manifestations. It has been demonstrated that the predominant activity of the optically active isomers of chlorpheniramine is the dextro-isomer. The dextro-isomer is approximately two times more active than the racemic compound. Since dexchlorpheniramine is the dextro-isomer and active moiety of chlorpheniramine, its action and uses is similar to those of chlorpheniramine.
Peak blood levels were achieved at an average time of 3 hours after administration. The half life of Dexchlorpheniramine Maleate ranged from 20 to 40 hours. The drug when given is found to be extensively metabolised. The drug and metabolites were primarily excreted in the urine, with 19% of the dose appearing in 24 hours and total of 34% in 48 hours.
Pseudoephedrine is a physiologically active stereoisomer of ephedrine that acts directly on alpha-adrenergic receptors and to lesser degree, beta-adrenergic receptors. The alpha-adrenergic effects are believed to result from the reduced production of cyclic adenosine 3' , 5' monophosphate (cyclic 3' , 5' AMP) by inhibition of the enzyme adenyl cyclase activity.
Pseudoephedrine acts on alpha-adrenergic receptors in the nasal mucosa and releases norephedrine, hence producing vasoconstriction of the dilated nasal arterioles resulting in shrinkage of swollen nasal mucous membranes, reduction of tissue hyperemia, oedema and nasal decongestion and an increase in nasal airway patency. Drainage of sinus secretions is increased and obstructed Eustachian ostia may be opened. Relaxation of bronchial smooth muscle by stimulation of beta-adrenergic receptors may also occur. Following oral administration of 30 mg pseudoephedrine hydrochloride effects are noted within 30 minutes with peak activity occurring at approximately one hour after administration and the effect persists for 4 to 6 hours.
Pseudoephedrine is absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite. It has half-life of several hours; elimination is enhanced and half-life accordingly shorter in acid urine.

Indications:
It is indicated for the relief of unproductive cough and nasal congestion due to common cold or allergy.

Contraindications:
Hypersensitivity to any of its ingredients.
Do not use in the newborn, in premature infants, in nursing mothers, in patients with severe hypertension or severe coronary, artery disease or in those receiving monoamine oxidase (MAO) inhibitors.

Side effects / Adverse reactions:
The most frequent adverse reactions are: sedation; dryness of mouth, nose and throat; thickening of bronchial secretions; dizziness. Other adverse reactions may include :

Dermatologic	:	Urticaria, drug rash, photosensitivity, pruritus.
Cardiovascular system	:	Hypotension, hypertension, cardiac arrhythmias, and palpitation.
Hematologic system	:	Hemolytic anemia, thrombocytopenia, agranulocytosis.
Nervous system	:	Disturbed coordination, nervousness, tremor, irritability, insomnia, vision disturbances, convulsions, headache, euphoria and dysphoria.
Gastrointestinal system	:	Epigastric distress, anorexia, nausea, vomiting, diarrhoea, constipation.
Urinary system	:	Urinary frequency, difficult urination, urinary retention.
Respiratory system	:	Tightness of chest and wheezing, shortness of breath.

Precautions / Warnings:
Sympathomimetics should be used with caution in patients with hypertension, hyperthyroidism, diabetes mellitus and cardiovascular disease. Antihistamines should be used with caution in patients with narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy and bladder neck obstruction. Antihistamines should not be used to treat lower respiration tract conditions including asthma. Not to be used for chronic persistent cough accompanying a disease state for cough associated with excessive secretions. Should be used with caution in patients with bronchial asthma, arrhythmias, glaucoma, ischemic heart disease and renal failure.
Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating machinery.
Use in pregnancy and lactation:
Safety during pregnancy has not been established.
It is not known whether this product is excreted in human milk and therefore caution should be exercised when administered to nursing mothers.
Use in children:
Safety and effectiveness of this product have not been established in children below 2 years.
Use in elderly:
Antihistamines may cause dizziness, sedation and hypotension in patients above 60 years. These patients are also more likely to have adverse reactions to sympathomimetics.
Elderly patients may be particularly sensitive to central nervous system effects.
Not recommended for children below 2 years.
Use with caution and on doctor's/pharmacist's advice in children 2 to 6 years of age.

Dosage:
Oral administration.
Children 6 to 11 years: 10 ml every 4 to 6 hours
Children 2 to 5 years: 5 ml every 4 to 6 hours
Not recommended for children below 2 years.
Use with caution and on doctor's/pharmacist's advice in children 2 to 6 years

Drug Interactions:
Anti-histamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquillisers, antianxiety agents, etc). These drugs may potentiate the sedative effect of dexchlorpheniramine. The action of oral anticoagulants may be inhibited by antihistamines. Monoamine oxidase inhibitors prolong and intensify the anti-cholinergic (drying) effects of antihistamines and potentiate the pressor effects of sympathomimetics. Pseudoephedrine-containing drugs should not be given to patients treated with a MAOI or within 10 days of discontinuing such treatment. Pseudoephedrine should not be used with ganglionic-blocking agents or with adrenergic-blocking agents. Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis.

Symptoms and Treatment for overdosage and antidote(s):
Dexchlorpheniramine overdosage effects may vary from central nervous system depression to stimulation to death. Toxic doses of pseudoephedrine may result in CNS stimulation, tachycardia, hypertension and cardiac arrhythmias; signs of CNS depression may occasionally be seen.
Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos and convulsive seizures.
Induce emesis if patient is alert and is seen prior to 6 hours following ingestion. Precautions against aspiration must be taken especially in infants and small children. Gastric lavage may be carried out although in some instances tracheostomy may be necessary prior to lavage. Naloxone hydrochloride 0.005mg/kg intravenous short-acting barbiturates may be indicated. Hypertensive responses and/or tachycardia should be treated appropriately. Oxygen, intravenous fluids and other supportive measures should be employed as indicated.

Pack size: A bottle of 60ml, 100ml and 120ml.

Storage conditions: Store at temperature 25ºC. Protect from light.

Shelf-life: 3 years.

Description: A clear, green syrup with blackcurrant flavour.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer:
Sunward Pharmaceutical Sdn. Bhd.
No. 9 ,11&17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

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