AMENDED DRAFT PACKAGE INSERT

POLARAX TABLET / SYRUP

Composition:	Polarax Tablet	Polarax Syrup
Dexchlorpheniramine maleate	2mg/tab	2mg/5ml

Pharmacology:
Dexchlorpheniramine maleate is an antihistamine with anticholinergic 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 24 hours. The drug when given orally is found to be extensively metabolized. The drug and metabolites were primarily excreted in the urine with 19% of the dose appearing in 24 hours and a total of 34% in 48 hours.

Indications:
Dexchlorpheniramine is indicated for the symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivities, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, amelioration of allergic reactions to blood or plasma and dermographism. They are also indicated as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

Dosage: Oral administration. All doses are to be taken after meals.

	Tablet	Syrup
Adults and children 12 years and above	1 tablet every 4 to 6 hours	5ml every 4 to 6 hours
Children 6 to 11 years	Half tablet every 4 to 6 hours	2.5ml every 4 to 6 hours
Children 2 to 5 years	Quarter tablet every 4 to 6 hours	1.25ml every 4 to 6 hours

Drug Interactions:
Monoamine oxidase (MAO) inhibitors prolong and intensify the effects of antihistamines; severe hypotension may occur. Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbiturates or other central nervous system depressants may potentiate the sedative effect of dexchlorpheniramine. The action of oral anticoagulants may be inhibited by antihistamines.

Precautions / Warnings:
Dexchlorpheniramine maleate may produce drowsiness and impair mental alertness required for the performance of potentially hazardous activities such as driving or operating machinery.It should be used with caution in patients with a history of bronchial asthma, glaucoma, hyperthyroidism, cardiovascular disease and hypertension.Dexchlorpheniramine maleate may cause hypotension when given in conjunction with a monoamine oxidase inhibitor.Concomitant use of dexchlorpheniramine maleate with alcohol, tranquilizers and sedatives may have an additive effect.

Use in Pregnancy and Lactation:
There is no adequate and controlled studies to date for the use of dexchlorpheniramine maleate in pregnant and nursing mother. Hence the drug should be used in these situations only when clearly needed.

Contraindications:
Hypersensitivity to dexchlorpheniramine maleate or other antihistamines of similar chemical structure. The drug should not be used in newborn or premature infants because of the possibility of severe reactions such as convulsion. Antihistamines should not be used to treat lowerrespiratory tract symptoms. They are also contraindicated for use in conjunction with monoamine oxidase inhibitor therapy. The drug is contraindicated during an acute episode of asthma as it can reduce and thicken bronchial secretion resulting in respiratory passage obstruction. It is also contraindicated in patients with urinary retention as the anticholinergic effects of dexchlorpheniramine maleate may precipitate or aggravate the conditions.

Side Effects:
The most common effect, varying from slight drowsiness to sleep an including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and in-coordination. Other side effects include nausea, vomiting, diarrhoea or constipation, colic and epigastric pain, headache, blurred vision, difficulty in micturition, dryness of mouth, tightness of chest, heaviness and weakness of the hand, 'ringing' in the ears, anorexia and nightmares.

Symptoms and Treatment of overdosage antidote (s):
Manifestations of antihistamine overdosage may vary from central nervous system depression (sedation, apnea, diminished mental alertness, cardiovascular collapse) to stimulation (insomnia, hallucinations, tremors or convulsions) to death. Other signs and symptoms may be dizziness, tinnitus, ataxia, blurred vision and hypotension. Stimulation is particularly likely in children, as are atropine like signs and symptoms (dry mouth, fixed, dilated pupils, flushing, hyperthermia and gastrointestinal symptoms).
Treatment:
The patients should be induced to vomit, even if emesis had occurred spontaneously. Pharmacologic vomiting by the administration of ipecac syrup is the preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of eight to twelve fluid ounces of water. If emesis does not occur, within fifteen minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in infants and children. Following emesis any drug remaining in the stomach may be absorbed by activated charcoal administered as a slurry with water. If vomiting is unsuccessful or contraindicated gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice. Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis and therefore may be valueable for their action in rapid dilution of bowel content.
Treatment of signs and symptoms of overdosage is symptomatic and supportive. Stimulants (analeptic agents) should not be used. Vasopressors may be used to treat hypotension, short acting barbiturates, diazepam, paraldehyde may be administered to control seizures. Hyperpyrexia especially in children may require treatment with tepid water sponge baths or a hypothermic blanket. Apnea is treated with ventilatory support.

Storage condition: Store at or below 30°C. Protect from light.

Shelf-life : Syrup : 3 years.
Tablet : Bottle : 3 years
Blister pack : 2 years

Pack size: Syrup : A bottle of 60ml, 100ml and 120ml.
Tablet : A bottle of 180 tablets.
Blister pack : A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.

Pack size (export only) : Syrup : A bottle of 3.6 litres and 3.8 litres.
Tablet : A bottle of 1000 tablets.

Description : Syrup : A clear, orange-coloured syrup with pineapple flavour.

Description : Tablet : Oval, red standard, convex tablet with single score on one side only.

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

Product Manufacturer & Registration Holder:
Malaysia:
Sunward Pharmaceutical Sdn. Bhd.
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