POLARAX SYRUP/TABLET

Syrup : Each 5ml contains:- Dexchlorpheniramine maleate 2.0mg
Tablet: Each tablet contains:- Dexchlorpheniramine maleate 2.0mg

WARNING (FOR SYRUP): THIS PRODUCT CONTAINS TARTRAZINE WHICH MAY CAUSE ALLERGIC TYPE REACTIONS (INCLUDING BRONCHIAL ASTHMA) IN CERTAIN SUSCEPTIBLE INDIVIDUALS.

Pharmacology:
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 achived at an average time of 3 hours after administration. The half life of dexchlorpheniramine maleate range 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 maleate is indicated for the symptomatic treatment of seasonal hay fever, itching skin conditions in urticaria, sensitivity reactions and other allergic conditions.

Dosage:
Tablet:
Adults and children above 12 years: One tablet three to four times daily.
Children 6 to 11 years : Half a tablet, three to four times daily.

Syrup:
Adults and children above 12 years : One teaspoonful three to four times daily.
Children 6 to 11 years : Half a teaspoonful three to four times daily.
All doses are recommended to be taken after meals.

Usage during pregnancy:
The product should be used during the first and second trimester of pregnancy only if clearly needed.

Precautions / Warnings:
Dexchlorpheniramine maleate should be used with cautions in patients with a history of bronchial asthma, hyperthyroidism, cardiovascular disease,hypertension.
1) Dexchlorpheniramine may cause slight to moderate drowsiness. Patients are therefore advised group of antidepressant drugs known as monoamine oxidase inhibitors.
2) Alcohol or other sedative drugs may enhance the drowsiness caused by it.
3) Dexchorpheniramine maleate may cause hypotension when given in conjunction with a certain group of antidepressant drugs known as monoamine oxidase inhibitors.

Side Effects:
The side effects of dexchlorpheniramine maleate include: Urticaria, drug rash, excessive perspiration, chills, dryness of mouth, nose and throat, headache, excitation, insomnia, nervousness, irritability, blurred vision, difficult urination, early menses, thickening of bronchial secretions, tightness of chest, wheezing and nasal stuffiness.

Symptoms and treatment of overdosage and antidote:
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 gastic 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 valuable 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 conditions:
Tablet – Store at room temperature below 30°C.
Syrup – Store at or below 25°C. Protect from light.

Shelf life: Tablet – 5 years, Syrup – 2 years

Packing / Pack size:
Tablet – bottle pack & blister pack of 1000 tablets, bottle pack of 3000 tablets.
Syrup – bottle pack of 3.6 litres and 3.8 litres.

Description:
Tablet : Oval, convex, pink, plain tablet with single score on one side only.
Syrup : A clear, orange syrup with mango flavour

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

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Singapore:
Sunward Pharmaceutical Pte Ltd
11, Wan Lee Road
Singapore 627943
Tel: 6265 6022

Malaysia:
Sunward Pharmaceutical Sdn. Bhd.
No.9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.
Tel : (07)-236 7531, 236 7967, 236 7972 Fax : (07)-236 7532