ANPRODEX TABLETS 2MG

NAME AND STRENGTH OF ACTIVE SUBSTANCE:
Each tablet contains :
Dexchlorpheniramine maleate…….. 2mg

PRODUCT DESCRIPTION:
A red, scored, flat of oval tablet (7.7x5.25mm)

PHARMACODYNAMICS:
Dexchlorpheniramine is the dextrorotarory isomer of chlorpheniramine maleate, which is a racemic mixture, and has approximately twice the activity of chlorpheniramine on a weight basis. Dexchlorpheniramine maleate is a histamine H1-receptor antagonist, used in symptomatic relief of hypersensitivity reactions and in pruritic skin disorders. The antihistaminic activity appears to compete with histamine for cell receptor sites on effector cells.

PHARMACOKINETICS:
Chlorpheniramine maleate appears to be well absorbed following oral administration. However, the drug undergoes substantial metabolism in the GI mucosa during absorption and on first pass through the liver. Limited data indicate that about 25-45% of a single oral dose of chlorpheniramine as conventional tablets, reaches the systemic circulation as unchanged drug. Following oral administration, chlorpheniramine appears in plasma within 30-60 minutes and the peak plasma concentration of the drug occurs within 2-6 hours.

Distribution of chlorpheniramine into human body tissues and fluids has not been fully characterized. Following IV administration in rabbits, highest concentration of the drug are attained in lungs, heart, kidneys, brain, small intestine, and spleen, with lower concentrations in the large intestine, muscle, stomach, adrenals, fat, liver and mesentery. Following IV adminstration in humans, chlorpheniramine undergoes rapid and extensive distribution with an average apparent steady-state volume of 2.5-3.2L/kg in adults and 3.8L/kg in children. Chlorpheniramine is distributed into saliva and the drug/or its metabolite appear to be distributed in small amounts in bile. Invitro, chlorpheniramine is approximately 69-72% bound to plasma protein.

Chlorpheniramine is rapidly and extensively metabolized, and undergoes substantial metabolism in the GI mucosa during absorption and on first pass through the liver following oral adminstration. It undergoes N-dealkylation to form monodesmethylchlorpheniramine and didesmethylchlorpheniramine, but is principally metabolized to other (at least 2) unidentified metabolites. Chlorpheniramine and its metabolites are apparently excreted almost completely in urine. Urinary excretion of parent molecule and its metabolites varies with the urinary pH and urine flow, decreasing substantially as urinary pH increases and urine flow decreases.

In adults with normal renal and hepatic function, the terminal elimination half-life of chlorpheniramine reportedly ranges from 12-43 hours and in childrens it was found to be 9.6-13.1 hours (range : 5.2-23.1 hours).

INDICATION:
Symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild and uncomplicated allergic skin manifestations of urticaria and angioedema, amelioration of allergic reactions to blood plasma. Therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled. Skin conditions, eg., allergic eczema, atopic dermatitis, contact dermatitis, insect bites, dermographism and drug reactions.

RECOMMENDED DOSAGE:

Adult : 2mg three to four times a day. Max : 12mg/day.
Children : 12 years of age and above : 2mg three to four times a day. Max : 6mg/day.
: 6-12 years : 1mg three to four times a day. Max : 6mg/day.

ROUTE OF ADMINISTRATION:

Oral route

CONTRAINDICATIONS:

Newborn and premature infants, patients receiving MAOI therapy and those who have shown hypersensitivity or idiosyncrasy to any of the components or to other drugs of similar chemical structures.

WARNINGS AND PRECAUTIONS:

Dexchlorpheniramine maleate should be used with caution in patients with narrow angle glaucoma, pyloroduodenal obstruction (including stenotic peptic ulcer), urinary tract obstruction (including bladder neck obstruction and symptomatic prostatic hyperplasia), cardiovascular disease (including hypertension and tachycardia), in those with increased intraocular pressure and hyperthyroidism. Patients should be warned about engaging in activities requiring mental alertness, eg driving a car or operating appliances, machinery,etc. Antihistamines may cause dizziness, sedation and hypotension in patients over 60 years. May cause paradoxical excitation in pediatric patients and can result in hallucinations, coma, and death in overdose.

INTERACTIONS WITH OTHER MEDICAMENTS:

MOAI's 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.

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION:

Safety during pregnancy has not been established. It is not known whether dexchlopheniramine is excreted in human milk, therefore caution should be exercised when administered to nursing mothers. Because of the potential for serious adverse reactions to antihistamines in nursing infants, a decision should be made whether to discontinue nursing or dexchlorpheniramine, taking into account the importance of the drug to the women.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS:

Slight to moderate drowsiness is the most frequent adverse effect of dexchlorpheniramine maleate. Other possible adverse effects of antihistamines include cardiovascular, hematologic, neurologic, gastrointestinal, genitourinary and respiratory reactions. General side effects e.g, urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat have been reported.

OVERDOSE AND TREATMENT:

The patient should be carefully observed for the above symptoms (i.e, side effects) and subsequent measures should be taken in case of overdose. In severe overdosages with antihistamines, the stomach should be emptified. Emetics may be tried if the patient is alert and there are no symptoms of toxicity, but may be ineffective due to the antiemetic activity of the antihistamine. Supportive treatment include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids. Forced diuresis is of little value since many antihistamines are rapidly metabolised and only traces are recovered in the urine.The benefits of peritoneal dialysis or haemodialysis also appear to be limited. CNS depressants should be avoided.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage Form : Tablet
Packing size : Blister pack : 100x10's.

NAME AND ADDRESS OF MANUFACTURER AND PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

14/06/2022