

ANTIGRAIN

PIZOTIFEN MALATE BP

Compositions:

Antigrain Tablet: Each film-coated tablet contains Pizotifen Malate BP 0.725 mg equivalent to Pizotifen 0.50 mg Antigrain TS Tablet: Each film-coated Tablet contains Pizotifen Malate BP 2.175 mg equivalent to Pizotifen 1.50 mg

Pharmacology:

Pizotifen BP (as Malate) is a tri-cyclic compound possessing structural similarities to cyproheptadine and tri-cyclic antidepressants. It is given orally for the prophylaxis of migraine and for the prevention of headache attacks during cluster periods. It is not effective in acute attacks of migraine. The prophylactic effect of Antigrain (Pizotifen) is associated with its ability to modify the humoral mechanisms of headache. It inhibits the permeability increasing effect of serotonin and histamine on the affected cranial vessels, thereby checking the transudation of plasmakinin so that the pain threshold of the receptor is maintained at 'normal' levels. In the sequence of events leading to migraine attack, depletion of plasma serotonin contributes to loss of tone of extracranial vessels. Pizotifen inhibits serotonin re-uptake by the platelets, thus maintaining plasma serotonin and preventing the loss of tone and passive diffusion of the extracranial arteries.

Dosage And Administration:

Adults: Usually 1.5 mg daily at night as a single dose or in three divided doses. Dosage should be adjusted to individual patients requirements up to a maximum of 4.5 mg daily. Maximum single daily dose at night 3 mg. Children: Up to 1.5 mg daily, usually as a divided dose. Use of 1.5 mg at a time is not recommended, but up to 1 mg has been given as a single daily dose at night.

Contraindications:

Hypersensitivity to Pizotifen. Although its anticholinergic activity is relatively weak, Pizotifen should not be administered in the presence of narrow-angle glaucoma or prostate hypertrophy. Antigrain should not be given to children under 2 years of age.

Warning And Precaution:

Urinary retention, renal impairment, pregnancy, breast feeding should be taken in consideration. Drowsiness may affect the performance of skilled (e.g. driving), effect of alcohol is enhanced.

Side Effects:

The most commonly occurring side effects are drowsiness, Increased appetite, weight gain. Occasionally nausea, dizziness. CNS stimulation may occur in children.

Use in Pregnancy and Lactation:

As clinical data with Pizotifen in pregnancy is very limited, it should only be administered during pregnancy under compelling circumstances. It's use in nursing mother is not recommended

Drug Interaction:

Tolerance to alcohol may be lowered. Pizotifen may increase and prolong the drowsiness that occurs as an adverse effect of concurrently use of tranquilizers, hypnotics and antidepressants. Pizotifen should not be used in patients receiving monoamine oxide (MAO) inhibitors.

Overdosage:

Symptoms of overdosage may include drowsiness, dizziness, hypotension, dryness of mouth, confusion, excitatory states (in children), ataxia, nausea, vomiting, dyspnoea, cyanosis, convulsions (particularly in children), coma and respiratory paralysis. Treatment: Administration of activated charcoal is recommended; in case of very recent intake, gastric lavage may be considered. Severe hypotension must be corrected (CAVE: adrenaline may produce paradoxical effects). If necessary, symptomatic treatment including monitoring of the cardiovascular and respiratory systems. Excitatory states or convulsions may be treated with short acting benzodiazepines.

Storage:

Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:

Antigrain Tablet: Each box containing 5x10's tablets in blister strip. Antigrain TS Tablet: Each box containing 5x10's tablets in blister strip.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.