

Pizofen™

Pizotifen BP

COMPOSITION :

Pizofen™ Tablet : Each film coated tablet contains Pizotifen malate BP equivalent to Pizotifen 0.5 mg

Pizofen™ TS Tablet : Each film coated tablet contains Pizotifen malate BP equivalent to Pizotifen 1.5 mg

PHARMACOLOGY :

Pizofen™ is the brand name of Pizotifen, which is a tricyclic compound having antiserotonergic and antihistaminergic effects together with a weak anticholinergic action. Pizotifen inhibit the permeability-increasing effects of serotonin & histamine on the affected cranial vessels, thereby checking the transudation of plasma kinin so that the pain threshold of the receptors is maintained at normal levels. In the sequence of events leading to the migraine attack, depletion of plasma serotonin contributes to loss of tone in the extra cranial vessels. Pizotifen inhibits serotonin re-uptake by the platelets, thus maintaining plasma serotonin and preventing the loss of tone & passive distension of the extra cranial arteries.

INDICATION :

It is used as prophylactic treatment of vascular headaches of the migraine types, such as classic migraine, common migraine and cluster headache.

DOSE AND ADMINISTRATION :

Adult : Usually 1.5 mg daily, which may be taken as a single dose at night or in three divided doses. Dose should be adjusted to individual patient's requirements. Upto a maximum of 4.5 mg may be given as a single dose daily.

Children : Dose is 1 mg as a single dose at night using 0.5 mg tablet. Maximum dose is upto 1.5 mg daily usually in divided dose.

Or as directed by the physician.

DURATION OF TREATMENT :

3-6 months; minimum one month to observe the benefit.

CONTRAINDICATION :

Although its anticholinergic activity is relatively weak, Pizotifen should probably not be administered in presence of narrow-angle glaucoma or prostate hypertrophy. It should not be given patients with hypersensitivity.

WARNING & PRECAUTION :

Patients should be cautious about the possibility of drowsiness and informed of its significance in driving vehicles and operation of machineries. The central effects of sedatives, hypnotic, antihistamine and alcohol may be enhanced by Pizotifen. Dose adjustment may be required in patients with kidney insufficiency.

SIDE EFFECTS :

Drowsiness is the most common side effect and increased appetite, which may lead to increase in body weight. Other side effects are dizziness, dry mouth, nausea, constipation which are rare. CNS stimulation may occur in children.

USE IN PREGNANCY AND LACTATION :

Information of using Pizotifen in pregnancy is limited, so it should only be used during pregnancy under compelling circumstances and it is not recommended to the nursing mother.

USE IN CHILDREN & ADOLESCENT :

Children (< 12 years of age): It is contraindicated in children under the age of 12.

Adolescent: There is limited evidence of supporting the safety and efficacy of Pizofen in adolescent 12-17 years of age, therefore pizofen should be used with caution in this age group.

DRUG INTERACTION :

The central effects of sedatives, hypnotics, antihistamines (including certain common cold preparations) and alcohol may be enhanced by pizotifen.

OVERDOSE :

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.

STORAGE :

Store below 30°C, protected from light & in a dry place. Keep all medicine out of the reach of children.

PACKAGE :

Pizofen™ Tablet : Box containing 10X10 tablets in blister pack.

Pizofen™ TS Tablet : Box containing 5X10 tablets in blister pack.

Manufactured by:

Navana Pharmaceuticals Ltd.

Rupshi, Rupganj, Narayanganj, Bangladesh

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 **NAVANA PHARMA**
JAHURUL ISLAM COMPANY