

Pifen®

Pizotifen BP

Description

Pifen® contains Pizotifen BP (as Malate) which 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.

Mode of action

The prophylactic effect of Pizotifen (Pifen®) 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.

Composition

Pifen® 0.5 mg Tablet: Each film-coated tablet contains Pizotifen Malate BP 0.725 mg equivalent to Pizotifen BP 0.5 mg.

Pifen® 1.5 mg Tablet: Each film-coated tablet contains Pizotifen Malate BP 2.175 mg equivalent to Pizotifen BP 1.5 mg.

Indications

Pizotifen (Pifen®) is chiefly indicated for the prophylactic treatment of vascular headaches of the migraine type such as classical migraine, common migraine and cluster headache.

Dosage & administration

Adults: The initial adult dose is 1.5 mg daily, this may be taken at bed time as a single dose or in three divided doses. Dosage can be adjusted according to individual patients' requirements up to a maximum of 4.5 mg daily. Up to 3 mg may be given as a single daily dose.

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

It is contraindicated in patients hypersensitive to the drug. Pizotifen should probably not be administered in presence of narrow-angle glaucoma or prostate hypertrophy. Dosage adjustment may be necessary in patients with kidney insufficiency.

Side effects

The most commonly occurring side effects are drowsiness and an increase in appetite which may lead to increase in body weight. Other side effects such as dizziness, dry mouth, nausea and constipation have been reported infrequently. In children, CNS stimulation may occur.

Use in pregnancy & lactation

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

Precautions

Patients should be warned about the possibility of drowsiness and its significance in the driving of vehicles and the operation of machinery. The central effects of sedatives, hypnotics, antihistamines and alcohol may be enhanced. Caution is required in patient with urinary retention, closed angle glaucoma and renal impairment.

Drug interactions

Patients should be warned that their tolerance to alcohol may be lowered. Pizotifen may increase and prolong the drowsiness that occurs as an adverse effect of concurrently used tranquilizers, hypnotics and antidepressants. It should not be used in patients receiving monoamine oxidase inhibitors.

Storage

Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Pifen® 0.5 mg Tablet: Each carton contains 10X5 tablets in Blister pack.

Pifen® 1.5 mg Tablet: Each carton contains 10X3 tablets in Blister pack.

128-05



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.