Zeromig®

Pizotifen Malate BP Film Coated Tablet

DESCRIPTION

Zeromig® is a preparation of Pizotifen Malate. Pizotifen has powerful anti-serotonin and antitryptaminic properties, marked anti-histaminic effects and some antagonistic activity against kinins. It also possesses weak anti-cholinergic effects and sedative properties. Pizotifen also possesses appetite-stimulating properties. The prophylactic effect of Pizotifen in migraine is associated with its ability to modify 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 receptors is maintained at 'normal' levels. In the sequence of events leading to migraine attack, depletion of plasma serotonin contributes to loss of tone in the extracranial vessels. Pizotifen inhibits serotonin re-uptake by the platelets, thus maintaining plasma serotonin and preventing the loss of tone and passive distension of the extracranial arteries.

INDICATIONS

Prophylactic treatment of recurrent vascular headaches, including classical migraine, common migraine and cluster headache (periodic migrainous neuralgia).

DOSAGE AND ADMINISTRATION

Adults: Usually 1.5 mg daily. This may be taken as a single dose at night or in three divided doses. Dosage should be adjusted to individual patient requirements up to a maximum of 4.5 mg daily. Up to 3 mg may be given as a single dose.

Children: Up to 1.5 mg daily in divided dose. Use of 1.5 mg tablets is not recommended. The appropriate pediatric doses may be given using 0.5 mg tablets. Although up to 1 mg has been given as a single dose at night.

Use in Elderly: Clinical work has not shown elderly patients to require different dosage from younger patients.

CONTRAINDICATIONS

Hypersensitivity to the active substance.

PRECAUTIONS

Although the anticholinergic activity of Pizotifen is relatively weak, caution is required in the presence of closed angle glaucoma and in patients with a predisposition to urinary retention. Dosage adjustment may be necessary in patients with kidney insufficiency. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

USE IN PREGNANCY AND LACTATION

Pregnancy category B1. No embryotoxic or teratogenic effects were observed in animal studies and fertility was unimpaired.

Clinical data with Pizotifen in pregnancy are very limited; it should be administered in pregnancy only if the expected benefits outweigh any potential risks.

Animal studies show that Pizotifen enters the milk. Although the concentrations of Pizotifen measured in the milk of treated mothers are not likely to affect the infant, its use in nursing mothers is not recommended.

SIDE EFFECTS

The most commonly occurring side-effects are drowsiness and an increased appetite, which may lead to an increase in body weight. Other side effects such as dizziness, dry mouth, nausea and constipation have been reported infrequently. Rare instances of sleep disorders, depression and other mood disturbances have occurred. In children CNS stimulation may occur.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Zeromig® 0.5 Tablet : Box containing 5 strips of 10 tablets each. Each film coated tablet contains Pizotifen Malate BP equivalent to Pizotifen 0.5 mg.

Zeromig® 1.5 Tablet : Box containing 3 strips of 10 tablets each. Each film coated tablet contains Pizotifen Malate BP equivalent to Pizotifen 1.5 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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