# Migranil®

# Pizotifen

#### COMPOSITION

**Migranil**<sup>®</sup> 0.5 Tablet: Each film coated tablet contains Pizotifen 0.5 mg as Pizotifen Malate BP.

**Migranil**<sup>®</sup> 1.5 Tablet: Each film coated tablet contains Pizotifen 1.5 mg as Pizotifen Malate BP.

## **PHARMACOLOGY**

**Migranil**<sup>®</sup> contains Pizotifen which is a tri-cyclic compound possessing structural similarity to cyproheptadine and tri-cyclic antidepressant. It is given orally for the prophylaxis of migraine and for the prevention of headache attacks during cluster periods.

The prophylaxis effect of **Migranil**® (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. 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.

#### INDICATIONS

**Migranil**<sup>®</sup> (Pizotifen) is chiefly indicated for the prophylaxis treatment of vascular headaches of the migraine type such as classic migraine, common migraine and cluster headache.

#### **DOSAGE & ADMINISTRATION**

Adults: The initial 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 to individual patients' 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, 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.

#### CONTRAINDICATION AND PRECAUTION

It is contraindicated in patients who are 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 failure. Patients should be warned about the possibility of drowsiness and its significance in the driving of vehicles and the operation of machinery. Caution is required in patients with urinary retention, closed angle glaucoma and renal impairment.

#### SIDE FEFECTS

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.

### DRUG INTERACTION

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 anti-depressants. It should not be used in patients receiving monoamine oxidase inhibitors.

#### **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. Its use in nursing mother is not recommended.

#### STORAGE CONDITION

Store below  $30^{\circ}$  C in a cool and dry place, protected from light and moisture. Keep out of the reach of children.

#### **HOW SUPPLIED**

**Migranil**<sup>®</sup> 0.5 tablet: Box containing 50 tablets in blister pack. **Migranil**<sup>®</sup> 1.5 tablet: Box containing 30 tablets in blister pack.

Manufactured by

