Pitofen

Pizotifen Malate

COMPOTION:

Pitofen Tablet: Each film coated tablet contains Pizotifen Malate BP equivalent to Pizotifen 0.5 mg.

DESCRIPTION

Pitofen (Pizotifen), a tricyclic compound having antiserotoninergic and antihistaminergic effects together with a weak anticholinergic action, but a little or no activity on kinins or their liberators. At low concentrations, Pitofen® (Pizotifen) may potentiate the actions of serotonin.

INDICATIONS

Pitofen (Pizotifen) is indicated as prophylactic treatment of vascular headache of migraine type such as classical migraine, common migraine and cluster headache. It is also indicated in appetite loss of somatic or psychogenic origin in underweight patients, as an adjuvant to treatment of the underlying condition, such as infectious or parasitic diseases (including during convalescence), chronic diarrhea, anorexia nervosa, or depressive states in the elderly and mood disturbances in the elderly.

DOSAGE & ADMINISTRATION

For migraine: 1.5mg at night or 0.5 mg three times daily, adjusted according to response within the usual range 0.5-3 mg daily, maximum single dose 3 mg, maximum daily does 4.5 mg.

Appetite loss:

Children: Low starting doses, gradually increasing to a mean maintenance dosage of 0.025mg/kg/day in 2-3 divided doses, or as directed by the physician.

Adults: Starting dose of 0.5 mg/day, gradually increasing to 0.5 mg three times daily.

Mood disturbances in the elderly

A starting of 0.5 mg/day is recommended increasing-preferably in steps of 0.5 mg daily until the optimum level is reached. Doses up to 12 mg/day are well tolerated.

Side-effects

Antimuscarinic effects- drowsiness, increased appetite, weight gain. Occasionally nausea, dizziness, CNS stimulation, may occur in children.

CONTRAINDICATIONS

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

Cautions

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

USE IN PREGNANCY AND LACTATION

Information of using Pizotifen in pregnancy is limited, although no ill effects have been reported. The drug should therefore only be given during pregnancy if the potential benefit to mother justifies the potential risk to the foetus. The safety of Pizotifen during lactation has not been established, so mothers should avoid taking it when breast feeding.

DRUG INTERACTIONS

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 anti-depressants. Pizotifen should not be used in patients receiving monoamine oxidase (MAO) inhibitors.

HOW SUPPLIED:

Pitofen Tablet: Box containing 10X10 tablets in blister pack.

Manufactured by:

