

Promtil[®]

Prochlorperazine Maleate BP

Composition

Promtil[®] tablet: Each tablet contains Prochlorperazine Maleate BP 5 mg.

Pharmacology

Prochlorperazine is a dopamine & histamine antagonist. The mechanism of antiemetic activity is due to the blockade of histamine H₁ & dopamine D₂ neurotransmitter receptors in the chemoreceptor trigger zone and vomiting centre. It also has weak anticholinergic effect and prevents acid reflux by increasing the tone of the lower oesophageal sphincter.

Indication

- To control severe nausea and vomiting caused by radiation therapy, cancer chemotherapy, surgery, and other conditions.
- Relieving nausea, vomiting and attacks of dizziness or spinning sensations (vertigo) associated with Meniere's disease and other inner ear disorders.
- For the treatment of psychotic illness such as schizophrenia (hallucinations and hostility).
- Acute mania.
- For the short-term treatment of generalized non-psychotic anxiety.

Dosage & Administration

Antiemetic

Children (not recommended in children <10 kg or <2 years):

10-14 kg: 2.5 mg every 12-24 hours as needed; maximum: 7.5 mg/day

15-18 kg: 2.5 mg every 8-12 hours as needed; maximum: 10 mg/day

19-39 kg: 2.5 mg every 8 hours or 5 mg every 12 hours as needed; maximum: 15 mg/day

Adults:

Oral: 5-10 mg 3-4 times/day; usual maximum: 40 mg/day

Antipsychotic:

Children 2-12 years (not recommended in children <10 kg or <2 years):

Oral: 2.5 mg 2-3 times/day; increase dosage as needed to maximum daily dose of 20 mg for 2-5 years and 25 mg for 6-12 years

Adults:

Oral: 5-10 mg 3-4 times/day; doses up to 150 mg/day may be required in some patients for treatment of severe disturbances

Nonpsychotic anxiety: Oral: Adults: Usual dose: 15-20 mg/day in divided doses; do not give doses >20 mg/day or for longer than 12 weeks

Elderly: Initial: 2.5-5 mg 1-2 times/day; increase dose at 4 to 7 day intervals by 2.5-5 mg/day; increase dosing intervals (twice daily, thrice daily, etc) as necessary to control response or side effects; maximum daily dose should probably not exceed 75 mg in elderly; gradual increases (titration) may prevent some side effects or decrease their severity.

Prochlorperazine may be administered without regards of meal.

Contraindication

Hypersensitivity to prochlorperazine or any component of the formulation, severe CNS depression; coma; should not be used in children <2 years of age or <10 kg.

Precaution

Caution should be taken while performing tasks that require alertness, such as driving or using machinery. Use of alcohol can cause extreme drowsiness. This medication may increase sensitivity to sunlight. Prolonged sun exposure should be avoided and a sunscreen and protective clothing should be taken when anybody is exposed to the sun. This medication can reduce sweating making more susceptible to heat stroke.

Pregnancy & lactation

No evidence of adverse effects of this drug has been reported during pregnancy & lactation.

Side effects

Drowsiness, jaw, neck, and back muscle spasms, fine worm-like tongue movements, rhythmic face, mouth, or jaw movements, slow or difficult speech, difficulty swallowing, restlessness and pacing, tremors, shuffling walk, skin rash, yellowing of the skin or eyes.

Drug interaction

Alcohol, barbiturate & other sedatives may increase the CNS depressant action. Some drugs like Antacids, antiparkinson's drug, lithium may interfere the absorption of Prochlorperazine. This drug may interfere with the plasma concentration of Propanolol and Phenobarbital.

Overdosage

Symptoms of overdose include deep sleep, coma, extrapyramidal symptoms, abnormal involuntary muscle movements, and hypotension.

Storage

Store below 30⁰ C. Protect from light and moisture. Keep out of the reach of children.

How supplied

Promtil[®] tablet: Each box contains 300 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH