

COMPOSITION

Timotor® Tablet: Each tablet contains Trimebutine Maleate INN 100 mg.

PHARMACOLOGY

Trimebutine Maleate is a noncompetitive spasmolytic agent. It possesses moderate opiate receptor affinity and has marked anti-serotonin activity especially on 'mu' receptors. It induces regulation of spontaneous activity and increases synchronization between electrophysiological spikes and contractions in isolated guinea pig strips of colon and ileum. However, it does not alter normal motility, but regulates abnormal intestinal activity.

INDICATIONS

- Treatment and relief of symptoms associated with Irritable Bowel Syndrome
- Postoperative paralytic ileus in order to accelerate the resumption of the intestinal transit following abdominal surgery.

DOSAGE AND ADMINISTRATION

Children over 12 years and Adults: 1 or 2 tablets, 3 times/day before meals.

ADVERSE REACTIONS

Trimebutine Maleate is generally well tolerated. The infrequently reported adverse effects are as follows: dry mouth, foul taste, diarrhea, dyspepsia, epigastric pain, nausea, constipation, drowsiness, fatigue, dizziness, hot/cold sensations, headache etc.

CONTRAINDICATIONS

Patients with known hypersensitivity to Trimebutine Maleate or any excipient.

USE IN PREGNANCY AND LACTATION

Although teratological studies have not shown any drug related adverse effects on the course and outcome of pregnancy, the use of Trimebutine Maleate in pregnant women is not recommended.

It is not known if Trimebutine Maleate passes into breast milk. This medication should be used while breast feeding only if the potential benefits outweigh risks to the nursing infants.

DRUG INTERACTIONS

No other drug interactions have been observed during clinical trials or otherwise reported.

TREATMENT OF OVERDOSAGE

No evidence of overdosage have been reported to date. However, if overdosage should occur following oral administration, gastric lavage is recommended. Treatment should be made according to the symptoms observed.

STORAGE

Store in a cool and dry place, away from light and moisture.

HOW SUPPLIED

Timotor® Tablet: Box contains 50 tablets in blister pack.

Manufactured by

