

pharmaniaga®

**IDAMAN PHARMA MAGNESIUM TRISILICATE  
TABLET COMPOUND**

**DESCRIPTION**

Round, flat, bevel edged tablets and scored on one side.  
Colour: White

**Each tablet contains:**

Magnesium Trisilicate 250 mg  
Dried Aluminium Hydroxide 120 mg

*Preservative:*

Sodium Benzoate: 0.27mg

**ROUTE OF ADMINISTRATION**

Oral

**PHARMACODYNAMICS**

Magnesium Trisilicate and Dried Aluminium Hydroxide are both slow acting antacids and absorption from the gut of breakdown products is very limited. The action is virtually entirely the inactivation of gastric acid and the symptomatic relief in gastric hyper acidic peptic ulcers.

The reaction of the trisilicate is slow and prolonged, and the silica formed is in the gelatinous colloidal state. The antacid action is accordingly slow in onset but it is prolonged and powerful. The absorbent properties of the product are possibly due to the formation of the silica gel, which provides a protective coating over the walls of the stomach. Aluminium Hydroxide has neutralising and absorbent actions. It does not completely neutralise the stomach contents, but the pH achieved (3.4 to 4.0) is sufficient to inhibit the proteolytic action of pepsin. There is also some evidence that the aluminium ion may inhibit pepsin action independently of its pH effect.

**PHARMACOKINETICS**

Aluminium and Magnesium ions are not completely absorbed. Unreacted insoluble antacids pass through the intestines largely as such and are excreted in the faeces. The reacted portion of the antacids enters the intestine in the form of the cation. In the intestine, some of the cation is absorbed; that which is absorbed has the same effect on the systemic bicarbonate pool as an equivalent amount of  $\text{NaHCO}_3$  because an equivalent amount of  $\text{HCO}_3^-$  returns to the systemic bicarbonate pool. Unabsorbed cation does not spare enteric  $\text{NaHCO}_3$  because an equivalent amount of  $\text{HCO}_3^-$  or  $\text{CO}_2$  is consumed in the formation of insoluble Hydroxides or Carbonates.  $\text{Al}^{3+}$  may be thought of as reacting with  $\text{CO}_3^{2-}$  to form an unstable  $\text{Al}_2(\text{CO}_3)_3$  intermediate which is then transformed into basic Aluminium Carbonates, Aluminium Hydroxide and Oxyaluminium Hydroxide. Some of Mg is eliminated in the faeces as  $\text{Mg}(\text{OH})_2$ . The remainder of unabsorbed  $\text{Mg}^{2+}$  is eliminated mostly as soluble salts such as the Chloride and Bicarbonate. Small amounts of the cations are also eliminated as sundry other insoluble compounds such as soaps, Phosphates, and so forth.

**INDICATIONS**

1) For symptomatic relief of stomach upset associated with hyperacidity (heartburn, acid indigestion and sour stomach).

- 2) For hyperacidity associated with gastric and duodenal ulcer.
- 3) For symptomatic treatment of gastroesophageal reflux disease.

**RECOMMENDED DOSAGE**

For oral administration. The tablets should be chewed before swallowing.

**Adults:** One or two tablets to be chewed when required (usually between meals and at bedtime).

**Children:** Not recommended for use in children.

**CONTRAINDICATIONS**

In patients with severe renal function impairment, hypersensitivity, acute porphyria or hypophosphataemia.

**ADVERSE REACTIONS**

There is a risk of renal rickets or osteomalacia in persons with a low phosphate diet or in the case of excessive doses due to the reaction between the soluble Aluminium Chloride and dietary phosphate to form an insoluble Aluminium Phosphate. Prolonged use or large doses may lead to bone pain or swelling of wrists or ankles, muscle weakness or unusual tiredness.

Antacids affect bowel mobility and secretions. Severe continuing constipation with large doses and feeling of discomfort and loss of appetite. Occurrence of diarrhea due to the formation of soluble salts of magnesium.

In patient with impaired renal function and gastrojejunal stoma, rapid absorption of magnesium may result in hypermagnesaemia, hypotension, ECG changes, sedation, confusion and in severe cases, respiratory paralysis and anergic cardiac pre-systole.

Long-term, excessive use has been associated with the development of silica-based renal calculi.

Hypersensitivity reactions: rash, pruritus, swelling face and periorbital oedema.

**WARNINGS AND PRECAUTIONS**

- 1) Antacids should not be given to young children (up to 6 years old of age) unless prescribed by a physician. Since children are not usually able to describe their symptoms precisely, proper diagnosis should precede the use of an antacid. This will avoid the complication of an existing condition (e.g. appendicitis) or the appearance of severe adverse effects. In very young children who are receiving magnesium containing antacids, there is risk of hypermagnesemia, especially in dehydrated children or in those with renal failure.
- 2) Metabolic bone disease commonly seen in the elderly may be aggravated by the phosphorus depletion, hypercalciuria, and inhibition of absorption of intestinal fluoride caused by the chronic use of aluminium containing antacids.
- 3) Risk-benefit should be considered when the following medical problems exist: Appendicitis or symptoms of appendicitis, undiagnosed gastrointestinal or rectal bleeding, ulcerative colitis, colostomy, diverticulitis, ileostomy, constipation, fecal impaction, chronic diarrhoea, gastric outlet obstruction, haemorrhoids intestinal obstruction and renal function impairment.

- 4) Do not take more than 8 tablets in a 24-hour period or 8 tablets/day for more than 2 weeks except under the advice and supervision of physician.
- 5) Frequent or regular use should only be on the advice of a physician.
- 6) This product also contains Sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- 7) Caution is necessary when giving to patients receiving antacids. Gastrointestinal absorption can be reduced by absorption of insoluble antacids or changes in gastric emptying time and the effects of a drug may be diminished or enhanced in the intestinal pH, or by the formation of complexes.

#### **PREGNANCY & LACTATION**

There is no evidence that orally administered Magnesium Trisilicate or Aluminium Hydroxide has adverse effects on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.

Caution should be exercised when prescribing to pregnant women.

Magnesium is not well absorbed and although small amounts may be found in breast milk, they are unlikely to cause problems in breastfed infants although they may cause diarrhoea. Aluminium is unlikely to cause problems in breastfed infants.

#### **INTERACTIONS WITH OTHER MEDICAMENT**

Combinations containing any of the following may also interact with this medication; Amphetamine, quinidine, anabolic steroids, oral coumarin or thioxanthenes, vitamin D including calcitriol. May reduce the absorption and effect of other medicines, therefore, should not be taken at the same time as other medicines. Examples of other medications which may be affected include, but are not limited to ACE inhibitors, salicylates e.g. aspirin, atazanavir, azithromycin, barbiturates, bile acids, bisphosphonates, cephalosporin antibiotics, fluoroquinolone antibiotics, chloroquine and hydroxychloroquine, deflazacort, digoxin, dipyridamole, eltrombopag, erlotinib, fexofenadine, gabapentin, iron preparations, isoniazid, itraconazole, ketoconazole, lansoprazole, levothyroxine, lithium, methenamine, mycophenolate, nitrofurantoin, penicillamine, phenothiazines, phenytoin, proguanil, rifampicin, rosuvastatin, sulpiride, tetracyclines, tipranavir, cimetidine, pivampicillin, ulipristal, (avoid use with antacids). With mexiletine plasma concentrations may be increased. There is a risk of metabolic alkalosis when oral magnesium salts are given with polystyrene sulfonate resins.

#### **SYMPTOMS AND TREATMENT OF OVERDOSAGE**

**Symptoms** : Symptoms are unlikely.

**Treatment** : Treatment if any would be merely supportive.

#### **PACK SIZE**

Blister Pack of 10's (3 Strips of 10 Tablets)

#### **STORAGE CONDITIONS**

Store below 30°C; Protect from light and moisture.

#### **INSTRUCTIONS FOR USE**

- 1) Do not take this product if you are presently taking a prescribed antibiotic drug containing any form of tetracycline.
- 2) Do not swallow whole. Must be chewed.
- 3) For best results follow by a half glass of water or other liquid.
- 4) Be alert to the possible laxative effect.
- 5) Possible interference with test using radiopharmaceuticals. Need to inform physician of using antacid.
- 6) Regular visits to physician to check progress of therapy if taking large doses or taking regularly for long period of time.

#### **SHELF LIFE**

Product should not be used beyond the expiry date imprinted on the product packaging.

#### **REGISTRATION NO.**

MAL21056002X

#### **KEEP MEDICINES OUT OF REACH OF CHILDREN JAUHI UBAT-UBATAN DARI KANAK-KANAK**

For further information, please consult your doctor or your pharmacist.

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Lt-304.01 Product Registration Holder and Manufacturer

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