SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Compound Magnesium Trisilicate Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: Magnesium trisilicate BP 250.00 mg and dried aluminium hydroxide gel BP 120.00 mg.

3 PHARMACEUTICAL FORM

Compound magnesium trisilicate tablets are white, normal convex tablets engraved with the company Logo on one side and A193 on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of dyspepsia.

4.2 Posology and method of administration

Route of administration: Oral

ADULTS, ELDERLY AND CHILDREN OVER 14 YEARS:
One to two tablets three times daily, one hour after meals and at bedtime or as required.

CHILDREN 10 TO 14 YEARS:
One tablet three times daily.

CHILDREN UNDER 10 YEARS:
Not recommended.

If symptoms persist for longer than 7 days, consult your doctor.

4.3 Contraindications

1. Renal failure

2. Hypophosphataemia

4.4 Special warnings and precautions for use

If renal function is impaired, hypermagnesaemia may result.

Symptoms of hypermagnesaemia may include flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.

If symptoms persist for longer than 7 days, consult your doctor.

Patients with rare hereditary problems of fructose or galactose intolerance, the LAPP lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of antacids reduces the absorption of ciprofloxacin, pivampicillin, rifampicin, most tetracyclines, itraconazole, ketoconazole, chloroquine, hydroxychloroquine, phenothiazines, phenytoin, oral iron, penicillamine and diflunisal. Concurrent use of antacids reduces the effectiveness of the ulcer healing drug sucralfate.

Concurrent use of antacids increases the excretion of aspirin, flecainide, mexiletine and quinine.

4.6 Fertility, Pregnancy and lactation

Safety of Compound Magnesium Trisilicate has not been established. However, as with all medicines, use during early pregnancy should be avoided. Use during later pregnancy and lactation is not considered to be a hazard.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

May cause nausea, vomiting, constipation or diarrhoea. If renal function is impaired, hypermagnesaemia may occur.

Large doses or even normal doses in patients with low phosphate diets may lead to phosphate depletion accompanied by increased resorption and urinary excretion of calcium with the risk of osteomalacia. Nephrolithiasis may also follow chronic use in patients with impaired renal function.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms of overdose include hypophosphataemia, anaemia, exacerbation or even initiation of osteodystrophy, proximal, myopathy, osteomalacia, encephalopathy, dementia, difficulty in urination or defaecation, depression of deep tendron reflexes, drowsiness, heart block and respiratory paralysis.

Treatment entails administration of 10-20ml of a 10% solution of calcium gluconate which reverses the heart block and respiratory depression induced by magnesium poisoning.

In severe cases intermittent peritoneal dialysis using a fluid free of magnesium may be necessary.

Aluminium toxicity may be treated by removal of aluminium with desferrioxamine.
Other symptomatic measures may be carried out if required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antacids react chemically to neutralise or buffer existing quantities of stomach acid resulting in increased pH of stomach contents thus providing relief of hyperacidity symptoms. They have no direct effect on acid output. Compound Magnesium Trisilicate Tablets contain two antacids namely aluminium hydroxide gel and magnesium trisilicate. Magnesium trisilicate is too insoluble and is a relatively weak antacid. Antacid action is exerted slowly therefore it does not provide a rapid symptomatic relief. However the

action is prolonged. It is also an effective gastro-intestinal adsorbent. The gelatinous silicon dioxide formed by the reaction of magnesium trisilicate with the gastric content is said to protect ulcerated mucosal surfaces and favour healing. Aluminium hydroxide is also an insoluble antacid. Food in the stomach delays gastric emptying and allows more time for aluminium hydroxide to react.

Alkalinization of gastric content increases gastric motility via gastrin. Aluminium ions relax the smooth muscle of stomach and delay gastric emptying. The relaxant effect is minimised in the presence of magnesium ions. Alkalinization of the gastric content increases lower oesophageal pressure and oesophageal clearance by a mechanism that is independent of gastrin. The use of Compound Magnesium Trisilicate Tablets does not significantly effect the motility of the bowel. The constipating effect of aluminium hydroxide is counter balanced by the diarrhoeal effect of magnesium trisilicate.

Aluminium and magnesium containing antacids are not completely absorbed, therefore they do not interfere with the acid-base balance to a great extent.

5.2 Pharmacokinetic properties

The insoluble aluminium compounds that constitute aluminium hydroxide are slowly and incompletely converted to aluminium chloride in the stomach. Some absorption of the aluminium salts occur from the gastro-intestinal tract, with some excretion in urine.

Unabsorbed aluminium hydroxide combines with phosphate present in the gut to form insoluble aluminium phosphate and some form carbonates and salts of fatty acids; all these salts are excreted in the faeces. Approximately 0.1 - 0.5 mg of aluminium ions may be absorbed from a standard daily dose of an aluminium containing antacid. In the presence of normal renal function this leads to about doubling of an average concentration of aluminium in plasma. However in patients with impaired renal function, higher concentrations occur.

During neutralisation magnesium trisilicate is converted to magnesium chloride and hydrated silica gel. Approximately 5% of the magnesium is absorbed and traces of the liberated silica may be absorbed and excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP, sucrose BP, maize starch BP, potable water, peppermint oil BP, magnesium stearate BP.

6.2 Incompatibilities

None.

6.3 Shelf life

- 3 years for product packed in plastic containers
- 2 years for product packed in blister packs

6.4 Special precautions for storage

Protect from heat, light and moisture.
Keep out of the reach of children.

6.5 Nature and contents of container

Compound magnesium trisilicate tablets are packed in opaque plastic containers composed of polypropylene tubes and polyethylene made tamper evident closures in pack sizes of 28, 42, 50, 56, 84, 100, 112, 250, 500 and 1000 tablets.

They are also packed in opaque plastic containers composed of either high density polypropylene or high density polyethylene with a tamper evident or child resistant tamper evident closure composed of high density polyethylene with a packing inclusion of standard polyether foam or polyethylene or polypropylene made filler for pack sizes of 28, 42, 50, 56, 84, 100, 112, 250, 500 and 1000 tablets.

In pack sizes of 28, 42, 56, 84 and 112 tablets only, the product is packed in blister packs of aluminium/opaque PVC. It is subsequently packed in printed boxboard cartons.

6.6 Special precautions for disposal

No special instruction for use/handling.

7. MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House, Sarum Hill,
Basingstoke, RG21 8SR, UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0216

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 June 2004

Date of last renewal: 2 February 2009

10 DATE OF REVISION OF THE TEXT

13/11/2024