SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Trisilicate Compound Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Magnesium Trisilicate 250 mg & Hydrated Aluminium Oxide 120 mg.

Excipients with known effect:
Sucrose 500 mg and Lactose 250 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.
Plain white, uncoated round tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of dyspepsia (heartburn and indigestion), and reflux oesophagitis. Can have a beneficial effect in promoting healing of duodenal ulcers.

4.2 Posology and method of administration

Posology
The tablets should be sucked or chewed before swallowing.

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

Not recommended for use in children.

Method of administration
For oral use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Acute porphyria or hypophosphataemia.

4.4 Special warnings and precautions for use

Use with caution in cases of renal impairment.

Frequent or regular use should only be on the advice of a physician.

This product contains sucrose and lactose.

Patients with rare hereditary problems of fructose or galactose intolerance, total 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

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, ulipristal (avoid use with antacids).

With quinidine plasma concentrations may be increased.

There is a risk of metabolic alkalosis when oral magnesium salts are given with polystyrene sulfonate resins.

4.6 Fertility, Pregnancy and 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. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

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 breast fed infants.

4.7 Effects on ability to drive and use machines

Magnesium Trisilicate Tablets has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

No significant side effects but there is a slight possibility of diarrhoea and belching. In patients with impaired renal function and gastrojejunal stoma, rapid absorption of magnesium may result in hypermagnesaemia, producing symptoms of muscular weakness, hypotension, ECG changes, sedation, confusion and in severe cases, respiratory paralysis and anergic cardiac presystole.

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

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage is most unlikely, and treatment if any would be merely supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A02A D – Combinations and complexes of aluminium, calcium and magnesium compounds

Magnesium Trisilicate and Dried Aluminium Hydroxide Gel 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.

5.2 Pharmacokinetic properties

The main effects of magnesium trisilicate are in the stomach, only traces of silicon dioxide, magnesium and aluminium are absorbed sytematically, and moieties are then excreted in the kidneys.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Lactose
Pregelatinised Maize Starch
Potato Starch
Stearic Acid
Peppermint Oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

HDPP tablet containers with LDPE closure.
Pack sizes 30, 50, 60, 100 & 500 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK Limited
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Ashford, Kent, England, TN23 1FB

8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0130

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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