SUMMARY OF PRODUCT CHARACTERISTICS COSMAG TABLET

1. Name of the Medicinal Product

Cosmag Tablets

2. Qualitative and Quantitative Composition

Each tablet contains 250 mg of Magnesium Trisilicate BP and 120 mg of Dried Aluminium Hydroxide BP

3. Pharmaceutical Form

Chewable Tablets

Light green circular flat bevelled-edge tablet embossed 'COSMAG' and stomach diagram on one side and plain on the other side with peppermint flavour

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

For oral administration. 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.

4.3 Contraindication

Hypersensitivity to any of the constituents.

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

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 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

No or negligible influence.

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 u

4.9 Overdose

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

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

A02AB10 – Antiacid

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 systematically, and moieties are then excreted in the kidneys.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sucrose BP

Potassium sorbate

Lime green color

Light magnesium oxide BP

Peppermint oil

Magnesium stearate BP

Rectified spirit

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place below 30ºC. Protect from light and moisture. Keep the

medicine reach out of the children.

6.5 Nature and contents of container

PVC 250 micron Blister Packing

6.6 Instructions for use, handling and disposal

No special requirements for disposal.

7 Manufacturer

Cosmos Limited

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