SUMMARY OF PRODUCT CHARACTERISTICS COSMAG TABLET

1 Name of the Medicinal Product

1.1 Proprietary Name

Cosmag Tablet

1.2 Strength

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

1.3 Pharmaceutical form

Chewable Tablets

2 Qualitative and Quantitative Composition

2.1 Qualitative declaration

Name of active ingredients
Magnesium Trisilicate BP
Dried Aluminium Hydroxide BP

2.2 Quantitative declaration

Name of ingredient	Quantity/Tablet (mg)
Magnesium Trisilicate BP	250 mg
Dried Aluminium Hydroxide BP	120 mg

For full list of Excipients, see section 6.1

3 Pharmaceutical Form

Chewable Tablets

Product description

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

Posology

Adults should take one or two tablets when required (usually between meals and at bedtime).

Not recommended for use in children

Method of Administration

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

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-isomaltose 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 Fertility, Pregnancy and lactation

Pregnancy

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.

Lactation

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.

Fertility

Cosmag tablet was not shown to alter fertility in animal studies

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

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 and the general public are

advised to report any suspected adverse reactions to the relevant drug authority regulator, through the relevant platforms.

4.9 Overdose

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

5 Pharmacological Properties

5.1 Pharmacodynamic Properties

Therapeutic class: Antiacid.

ATC code: A02AD01

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

5.3 Preclinical Safety Data

None stated.

6 Pharmaceutical Particulars

6.1 List of Excipients

Sucrose BP
Potassium sorbate
Lime green color
Light magnesium oxide
Peppermint oil
Magnesium stearate BP
Rectified spirit

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30˚C. Protect from light and moisture.

6.5 Nature and contents of container
PVC 250 micron Blisters in unit cartons or bulk plastic containers with literature insert

Available in pack sizes of 20 tablets, 25 X 4 tablets, 500 tablets, 1000 tablets and 10 x 10 tablets

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed off in accordance with local requirements.

7 Marketing Authorization Holder

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8 Marketing Authorization Number

514

9 Date of First Registration/Renewal of Registration

Date of First Registration: 26th September 1983

10 Date of Revision of Text

December 2025