Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Megacid Tablets

2. Qualitative and quantitative composition

Each Chewable Tablet contains
Magnesium Trisilicate BP (250 mg)
Dried Aluminium Hydroxide BP (120 mg)
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

White circular, flat, chewable, uncoated tablets having embossing "G" on one side of each tablet.

4. Clinical particulars

4.1 Therapeutic indications

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn, gastric hyperacidity. Treatment of indigestion. Relief of symptoms of heartburn and dyspepsia associated with gastric reflux in hiatus hernia, reflux oesophagitis and similar conditions.

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.

Should not be used in patients who are severely debilitated or suffering from kidney failure.

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 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 have 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: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems to the respective National Regulatory Authorities.

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations and complexes of aluminium, calcium and magnesium compounds,
ATC code: A02A D 01
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 SmPC**.**

6. Pharmaceutical Particulars

6.1 List of Excipients
Sucrose (Sugar) BP
Calcium Carbonate Light BP
Gelatine BP, Gum Acacia BP
Methyl Paraben BP
Propyl Paraben BP
Sodium Saccharine BP
Peppermint oil
Purified Talc BP
Magnesium Sterate BP
Maize Starch BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

3 years

6.4 Special Precautions for storage

Store in a cool and dry place below 30°C.

6.5 Nature and Content of container

Alu-Pvc Blisters of 10 Tablets (10X 10's)

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
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8. Marketing Authorization Number
H2007/10139

9. Date of first authorization/renewal of the authorization
14th June, 2026

10. Date of revision of the text
14th June, 2026