

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Krisacid Tablets (Compound Magnesium Trisilicate Tablets BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Magnesium Trisilicate BP 250 mg

Dried Aluminum Hydroxide BP 120 mg.

Peppermint flavor

Excipients with known effect: For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral tablet.

Off-White colour, round shaped uncoated tablets, on one side KRISACID embossed with G and other side plain.

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 before swallowing.

Adults: One or two tablets to be sucked 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 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.

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 systematically, 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

Maize Starch, Dibasic Calcium Phosphate, Sucrose, Gelatin, Sodium Sacharine, Methyl Paraben sodium, Propyl Paraben sodium, Magnesium Stearate, Purified Talc, Colloidal Silicon Dioxide (Aerosil) & Peppermint Oil

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. Protect from direct sunlight.

6.5 Nature and contents of container

The tablets are packed in Alu/PVC blister and inserted in a mono carton.
Pack sizes: 12x8 Tablets

6.6 Special precautions for disposal

Not applicable.

7. MANUFACTURER NAME

Krishat Pharma Industries Limited
KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State,
NIGERIA.
Email: info@krishatpharma.com