SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

MeCure's Antacid Tablet (Compound Magnesium Trisilicate Tablets)

2. Qualitative and quantitative composition

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

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet

White, round and flat shaped uncoated tablets having embossed with "M" on one side and the other side is plain.

4. Clinical particulars

4.1. Therapeutic indications

It is administered for the reduction of acidity and relief from post-operative gaseous distension, gastric ulcers.
The symptomatic relief of:
1. Dyspepsia
2. Heartburn
3. Flatulence.

4.2. Posology and method of administration

Posology
Adults including the elderly

Take one or two tablets 4 times each day

Take 20 minutes to one hour after meals and at bedtime or as required

Children
Aluminium Hydroxide Tablets are not recommended for children

For oral administration.

4.3 Contraindications

This product Should not be used in patients who are severely debilitated or suffering from kidney failure. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.Hypersensitivity to the active ingredients or to any of the excipients.

4.4 Special warnings and precautions for use

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly

Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets, may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of aluminium increase. In these patients, a long-term exposure to high doses of aluminium salts may lead to dementia, microcytic anemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may interact with a number of other drugs by altering their absorption and, sometimes, their elimination, thereby reducing their effectiveness. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. In order to minimise the risk of interactions, this product should not be taken within two to four hours of other medications (allow at least 4 hours before or 2 hours after erlotinib).

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).

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

4.6 Fertility, pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development (see section 5.3). The potential risk for humans is unknown. As there is no specific data for this product, it is recommended that Magnesium Trisilicate Mixture only be used in pregnancy on the advice of a doctor.

Caution should be exercised when prescribing to pregnant women as this product contains sodium

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Magnesium salts may cause diarrhoea in some patients. Magnesium carbonate and sodium hydrogen carbonate may cause stomach cramps and flatulence as a result of excess carbon dioxide production.

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

4.9 Overdose

Serious symptoms are unlikely following overdosage.
Reported symptoms of acute overdose with aluminium hydroxide salt include diarrhoea, abdominal pain,vomiting.
Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk(see section 4.4)
Aluminium eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency,haemodialysis or peritoneal dialysis is necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Magnesium trisilicate mixture is an antacid with slow neutralising action and mild laxative action.

5.2 Pharmacokinetic properties

Magnesium chloride and hydrated silica gel are formed during the neutralisation. About 5% of magnesium is absorbed and traces of liberated silica may be absorbed and excreted in the urine.

Any sodium hydrogen carbonate not neutralised in the stomach is absorbed and excreted as bicarbonate and sodium ions in the urine in the absence of a plasma deficit.

5.3 Preclinical safety data