1. NAME OF THE MEDICINAL PRODUCT

Magnomint Suspension - Magnesium Trisilicate 500mg
-Aluminium Hydroxide 250mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of suspension contains 500mg Magnesium Trisilicate
250mg Aluminium Hydroxide

3. PHARMACEUTICAL form

Magnomint is an oral suspension
It is a pink coloured, free flowing suspension having a minty flavour, sweet chalk like taste and without any visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn and gastric hyperacidity.

4.2 Posology and method of administration

Posology

Adults (including the elderly):
10 – 20 ml taken 20 minutes to one hour after meals and at bedtime or as required. It can be taken with water or milk if required.
Paediatric population:
Not recommended for children under 14 years.

Method of administration
For oral administration.
Shake before use.

4.3 Contraindications

It should not be used in patients who are severely debilitated or suffering from renal insufficiency, or if there is severe abdominal pain and/or the possibility of bowel obstruction. Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

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 both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia, microcytic anemia.
Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.
This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially "sodium free."

4.5 Interaction with other medicinal products and other forms of interaction

Antacids are known to interfere with the absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, levothyroxine, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, rosuvastatin.
Polystyrene sulphonate
Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).
Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.
Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Magnomint is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception. Caution should be exercised when prescribing to pregnant and lactating women.
Breast-feeding
Because of the limited maternal absorption, when used as recommended, aluminium hydroxide and magnesium salt combinations are considered compatible with lactation.

No effects on the breastfed newborns/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide and magnesium hydroxide is negligible.
Fertility
No fertility data is available.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data)

Immune system disorders
Not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions
Gastrointestinal disorders
Gastrointestinal side effects are uncommon.
Uncommon: diarrhoea or constipation (see section 4.4)
Frequency not known: Abdominal pain
Metabolism and nutrition disorders
Very rare: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment
*Frequency not known:*hyperaluminemia.
Hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets, which may result in increased bone resorption, hypercalciuria, osteomalacia (see section 4.4).
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.

4.9 Overdose

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.
Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination 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 and magnesium are 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

Pharmacotherapeutic group: Antacids; aluminium compound combinations
ATC code: A02AB10

Magnomint is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with Magnomint and this makes it especially suitable when long term therapy is necessary.

5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data

Non-clinical data are limited and are considered insufficient with respect to repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Paraben
Propyl Paraben
Carboxymethylcellulose Sodium
Sorbital
Aniseed oil
Polysorbate 80
Peppermint
Erythrosine FD & Red 3 Colour
Tabulose
Sodium saccharin

6.2 Incompatibilities

None stated

6.3 Shelf life

36 Months

6.4 Special Precautions for Storage

Do not store above 25°C.