1. NAME OF THE MEDICINAL PRODUCT

Al-Mag 120mg/250mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Dried Aluminium Hydroxide.....120mg
Magnesium Trisilicate BP.....250mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Oral solids/Tablets.
- A white circular tablet with "ALBEN" embossed on one side.

4. Clinical Particulars

4.1 Therapeutic indications

- For the management of hyperacidity, heartburn, dyspepsia, peptic ulcer and reflux oesophagitis.

4.2 Posology and method of administration

- Posology

As directed by the physician.

- Method of administration

  Oral.

  Tablet should be chewed before being swallowed.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients.
- Should not be used in patients who are severely debilitated or suffering from kidney failure.

4.4 Special warnings and precaution 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.
  If renal function is impaired hypermagnesaemia may result.

4.5 Interactions with other medicinal products and other forms of interaction

- Al-Mag Tablets may interact with many other drugs, both by alterations in gastric PH and emptying, and by direct absorption and formation of complexes that are not absorbed. Interactions can be minimized by giving the Al-Mag Tablets and any other medication 2 to 3 hours apart. Al-Mag Tablets should preferably not to be taken at the same time as other drugs as they may impair their absorption. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach.

4.6 Pregnancy and Lactation

- The potential risk for humans is unknown. As there is no specific data for this product, it is recommended that Al-Mag Tablets only be used in pregnancy on the advice of a doctor.

4.7 Effects on ability to drive and use machines

- None.

4.8 Undesirable effects

- Aluminium and Magnesium salts may cause constipation and diarrhea in some patients.

4.9 Overdose

- Overdose or excessive or prolonged intake of magnesium containing antacids may give rise to hypermagnesaemia. Symptoms of hypermagnesaemia include nausea, vomiting, flushing of the skin, thirst, drowsiness, hypotension, confusion, muscle weakness, CNS and respiratory depression, hyporeflexia, peripheral vasodilatation, bradycardia, cardiac arrhythmias, coma and cardiac arrest. Treatment of mild hypermagnesaemia is usually limited to restricting magnesium intake. In severe hypermagnesaemia, ventilatory and circulatory support may be required. Treatment should consist of the intravenous administration of calcium gluconate injection 10% at a dose of 10 – 20ml, to counteract respiratory depression or heart block. If renal function is normal, adequate fluids should be given to assist magnesium removal from the body. Haemodialysis may be necessary in patients with renal impairment or for whom other methods prove ineffective.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

- Aluminium hydroxide and magnesium trisilicate have antacid properties and are used to neutralise gastric acid.

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.
- Aluminium hydroxide reacts with hydrochloric acid in the stomach to form aluminium chloride, some of which is absorbed. Absorbed aluminium is eliminated in the urine. The majority of aluminium remains in the gastrointestinal tract and forms insoluble poorly absorbed aluminium salts including hydroxide, phosphate, carbonate and fatty acid derivatives, which are excreted in the faeces.

5.3 Preclinical safety data

- None Known.

6. Pharmaceutical particulars

6.1 List of excipients

- Starch(Bulk)
- Dicalcium Phosphate
- Talc
- Sugar
- Povidone
- Magnesium stearate
- Peppermint Oil
- Sodium Propyl Paraben
- Menthol
- Purified Water

6.2 Incompactibilities

- Not Applicable.

6.3 Shelf life

- Blister pack: 36 Months
- White plastic container: 36 Months

6.4 Special precautions for storage

- Store in a cool dry place protected from light and out of reach of children.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

- PVC/Aluminum blister packs.
- Pack size: 12 x 8 tablets in a monocarton; Pack of 1000 tablets in a white plastic container.

6.6 Special precautions for disposal<and other handling>

- None.

7. Applicant/Manufacturer

- Name: Alben Healthcare Industries Limited.
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