SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Of

DEMAG SUSPENSION

1. **Name of the medicinal product**

DEMAG SUSPENSION

2. **Qualitative and quantitative composition**

Each 5ml contains

Magnesium Carbonate Light	250mg
Magnesium Trisilicate	250mg
Sodium Bicarbonate	250mg

For the full list of excipients see section 6.1

3. **Pharmaceutical form**

Suspension

4. **Clinical particulars**

4.1 **Therapeutic indications**

For relief of the symptoms of indigestion, heartburn and dyspepsia.

4.2 **Posology and method of administration**

Oral.

RECOMMENDED DOSE

Adults and children over 12 years: two to four 5ml spoonfuls.

Children 5 to 12 years: one to two 5ml spoonfuls.

Directions for use: shake the bottle.

DOSAGE SCHEDULE

To be taken three times a day or as required.

4.3 **Contraindications**

Contraindicated in severe renal failure, hypophosphataemia and in patients who must control sodium intake e.g. congestive heart failure, hypertension, cirrhosis of the liver.

Should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

Hypersensitivity to any of the ingredients.

4.4 **Special warnings and precautions for use**

The product should be used with caution in patients with fluid retention. In view of the sodium hydrogen carbonate content, the product should also be administered extremely cautiously to patients with renal impairment, to patients receiving corticosteroids or patients with respiratory acidosis, eclampsia, or aldosteronism.

If renal function is impaired hypermagnesaemia may result giving the symptoms described under (4.9) overdose.

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 (see Section 4.4).

4.7 **Effects on ability to drive and use machines**

None.

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**

Overdose, or excessive or prolonged intake of magnesium containing antacids may give rise to hypermagnesaemia, and excessive administration of sodium hydrogen carbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with renal insufficiency.

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.

Symptoms of hypokalaemia and metabolic alkalosis include mood changes, tiredness, shortness of breath, muscle weakness and irregular heart beat. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality.

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. Metabolic alkalosis and hypernatraemia can be treated by appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium ions may be of particular importance.

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**

None Known.

6. **Pharmaceutical particulars**

6.1 **List of excipients**

- Carboxyl Methyl Cellulose
- Methyl Paraben
- Propyl Paraben
- Sucrose
- Saccharine Sodium
- Peppermint Oil
- Xanthan gum

6.2 **Incompatibilities**

None.

6.3 **Shelf life**

24 months

6.4 **Special precautions for storage**

Store below 30° C. Keep out of reach of Children

6.5 **Nature and contents of container**

100ml/200ml: Amber bottle

6.6 **Special precautions for disposal and other handling**

No special precaution apart from NAFDAC guidelines

7. **Marketing authorisation holder** / Manufacturer

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