BIORAJ PHARMACEUTICALS LIMITED	
BRAND NAME: BIOMAG TABLET	**GENERIC NAME:** Dried Aluminum Hydroxide BP……120mg Magnesium Trisilicate BP…….250mg
SUMMARY OF PRODUCT CHARACTERISTICS	

1. NAME OF THE MEDICINAL PRODUCT

Biomag Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Dried Aluminum Hydroxide Gel BP……120mg

Magnesium Trisilicate BP…….250mg

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral Solid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Biomag is recommended for the prevention and relief of abdominal pain, in the symptomatic management of gastric ulcer, duodenal ulcer and acid reflux.It also relieves epigastric pain and heartburn during the later stages of pregnancy.

Furthermore, Biomag is an effective remedy in conditions affecting the stomach which may not necessarily be related to hyperacidity; such conditions include indigestion and flatulence.

4.2 Posology and method of administration

Oral.

RECOMMENDED DOSE

2-3 tablets to be chewed 3-4 times daily in between meal or when symptoms arise.

DOSAGE SCHEDULE

To be taken three times a day or as required.

4.3 Contraindications

-Excessive use of Biomag and Magnesium; the symptoms of which include flushing of skin, hypotension due to pheripheral vasodialation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockage, muscle weakness, thirst among others.

-Excessive use of Biomag and Aluminum salts may prevent phosphate absorption leading to osteoporosis and osteomalacia.

-Care must be taken when administered to patients with renal insufficiency.

-Biomag may interfere with the absorption of other drugs such as tetracycline when taken simultaneously, if oral tetracycline has to be taken, it should be taken three hours before Biomag.

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.

The following warnings and precautions appear on the labels:

Keep out of the reach and sight of children.

Do not give to children under 5 years old unless your doctor tells you to.

Once opened use within 28 days.

If symptoms persist consult your doctor.

This medicine contains 73.5mg sodium (main component of cooking/table salt) in each 5ml dose. This is equivalent to 3.7% of the recommended maximum daily dietary intake of sodium for an adult.

It also contains sodium methyl and sodium propyl parahydroxybenzoates (E219 and E217) which may cause allergic reactions (possibly delayed).

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.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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, and shortness of breath, muscle weakness and irregular heartbeat. 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

Biomag Tablet 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

Sucrose (micromilling)

Sodium methyl paraben

Starch

Sodium propyl paraben

Sucrose for syrup

Magnesium stearate

Talcum powder

Peppermint powder

Peppermint oil

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium PVC blister Pack

12 x 8 Tablet

6.6 Special precautions for disposal and other handling

None.

7.0 MANUFACTURER

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