1.3.1 Summary of Product Characteristics (SmPC)

1. Name of drug product

Mist. Mag. Suspension

1.1 (Trade) name of product

Mist Mag Trisillicate B.P.C.

1.2 Strength

Composition:
Each 5 ml Contains
Mag Trisillicate 250 mg
Sodium Bicarbonate 250 mg
Light Mag. Carbonate 250 mg

1.3 Pharmaceutical Dosage Form

Syrup

2. QUALITATIVE & QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Composition:
Each 5 ml Contains
Mag Trisillicate 250 mg
Sodium Bicarbonate 250 mg
Light Mag. Carbonate 250 mg

2.2 Quantitative Declaration

Batch Formula:

Batch Size: 500 Ltr

SR. No	Ingredients	Specification	Label Claim (mg)	Qty/ 5 ml (mg)	Overages	Qty/batch (kg)	Ar. No.
1	**Mag. Trisillicate**	BP	25	25	--	25	RM09048
2	**Sodium Bicarbonate**	BP	25	25	--	25	RM081018
3	**Light Magnesium Carbonate**	BP	25	25	--	25	RM09003
4	**Peppermint Oil**	BP	--	120	--	12 L	RM080098
5	**Methyl Paraben**	BP	--	3.75	--	0.375	RM081038
6	**Propyl Paraben**	BP	--	1.91	--	0.191	RM084011
7	Demineralised Water	BP	--	5	--	500 L	RM081025
	Average Weight			200 ml		**Limit**	200.00 ± 2 %

3. PHARMACEUTICAL DOSAGE FORM

Mixture

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.

Take in a little water.

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

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.

Magnesium trisilicate mixture has a sodium content of 6.4 mmol equivalent to 73.4 mg/5 ml or 147mg/10 ml dose. This must be taken into consideration for patients on a controlled sodium diet.

This product contains sodium methyl and sodium propyl parahydroxybenzoates (E219 and E217 respectively) which may cause allergic reactions (possibly delayed).

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 product contains 6.4 mmol (or 147 mg) sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet.

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

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 Pharmacodynemic property

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 Pre-clinical safety data

None Known.

6. Pharmaceutical particulars

6.1 List of excipients

sodium methyl hydroxybenzoate (E219)

sodium propyl hydroxybenzoate (E217)

Menthol Flavour (Contains propylene Glycol)

Peppermint Flavour (Contains Propylene Glycol)

purified water

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

2 years

6.3 Special Precautions for Storage

Store below 25°C.

6.4 Nature and Contents of Container

200ml white coloured pet bottle with aluminium cap.

7. Marketing authorization holder / Manufacturer

KINGSIZE PHARMACEUTICALS NIG. LIMITED.
Off Km 15,
Old Enugu Road,
Anambra State,
Nigeria.

8. Marketing authorization number(s)

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text