SMPC FOR VISKO MIST MAGNESIUM TRISILICATE

1. Name of the medicinal product

VISKO Mist Magnesium Trisilicate

2. Qualitative and quantitative composition

Magnesium Carbonate Light	250mg/5ml
Magnesium Trisilicate	250mg/5ml
Sodium Hydrogen Carbonate	250mg/5ml

Excipients with known effects

Sodium methyl parahydroxybenzoate (E219)	32.5mg/5ml 3.4mg/5ml
Sodium propyl parahydroxybenzoate (E219) Saccharin sodium	2.50mg/5ml

For the full list of excipients see section 6.1

3. Pharmaceutical 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

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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.

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, 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 sodium methyl hydroxybenzoate sodium propyl hydroxybenzoate xanthan gum (E415)

SMPC FOR VISKO MIST MAGNESIUM TRISILICATE

Menthol Flavour

Peppermint Flavour

purified water

6.2 Incompatibilities None.

6.3 Shelf life 36months.

6.4 Special precautions for storage Store below 30°C.

6.5 Nature and contents of container

200ml: Plain pet bottle with white 28mm ROPP cap with Tamper Evident band.

6.6 Special precautions for disposal and other handling
None.

7. Marketing authorisation holder: VISKO PHARMACY LIMITED

8. Marketing authorisation number(s)
NA

9. Date of first authorisation/renewal of the authorisation
NA

10. Date of revision of the text
NA