SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Trisilicate Mixture B.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Trisilicate B.P. 250 mg/5 ml
Light Magnesium Carbonate B.P. 250 mg/5 ml
Sodium Bicarbonate B.P. 250 mg/5 ml

3. PHARMACEUTICAL FORM

Oral liquid

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Symptomatic relief of dyspepsia.
Symptomatic relief of reflux oesophagitis.
Symptomatic relief of gastric and duodenal ulcer.

4.2. Posology and Method of Administration

Adults and the elderly

Dose: 10 ml

The dose may be repeated every four (4) hours up to 4 times daily.

It should be used with caution in the elderly.

Children

It is not recommended for children.

Route of administration – oral

4.3. Contra-indications

Hypertension, renal impairment, patients on sodium restricted diet (in heart failure, hepatic and renal impairment and during pregnancy). It should be avoided in metabolic or respiratory alkalosis, hypocalcaemia and hypochlorhydria.

4.4. Special Warnings and Precautions for Use

None

4.5. Interactions with other Medicaments and other forms of Interaction

Gastrointestinal absorption of some drugs such as tetracyclines, digoxin, vitamins and iron may be reduced by adsorption; magnesium containing products may potentiate tubocurarine during anaesthesia. The effects of some drugs may be diminished or enhanced by alterations in intestinal pH or by the formation of complexes.

4.6. Pregnancy and Lactation

Like many other medicines, this product should be avoided during the first three months of pregnancy. This product has a high sodium content and should be used cautiously in patients on a sodium-restricted diet, and in toxaemia of pregnancy.

4.7. Effects on Ability to Drive and Use Machines

None.

4.8. Undesirable Effects

Magnesium salts may cause diarrhoea. Sodium bicarbonate and light magnesium carbonate may cause flatulence. Prolonged use of magnesium trisilicate may lead to development of siliceous calculus. Prolonged use of sodium bicarbonate may cause metabolic alkalosis.

4.9. Overdose

Hypermagnesaemia has rarely been reported after excessive use of, or overdosage with, magnesium containing antacids and laxatives, especially in the presence of renal insufficiency. Symptoms include flushing of the skin, thirst, hypotension, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscular weakness, respiratory depression, cardiac arrhythmia and cardiac arrest. Excessive bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may 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 cause sodium overloading and hyperosmolality.

Hypermagnesaemia may be treated by intravenous injection of calcium gluconate to counteract respiratory depression or heart block. In normal renal function, adequate fluids should be given to assist magnesium removal but dialysis may be necessary in renal impairment or severe hypermagnesaemia. Treatment of metabolic alkalosis and hypernatremia consists mainly of appropriate correction of fluid and electrolyte balance.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Magnesium trisilicate, light magnesium carbonate and sodium bicarbonate neutralise gastric acid.

5.2. Pharmacokinetic Properties

Magnesium salts are poorly absorbed following oral absorption. They are widely distributed and excreted unchanged mainly in the urine with very little faecal loss. Small amounts also cross the placenta and are excreted in breast milk.

Any sodium bicarbonate 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

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Nipastat Sodium HSE
Chloroform BP
Peppermint Oil BP
Potable Water HSE

6.2. Incompatibilities

None.

6.3. Shelf Life

Three years.

6.4. Special Precautions for Storage

Store below 25^{o}C.

6.5. Nature and Contents of Container

Dispensing pack

2 litre amber glass bottle with a white plastic screw cap with an EPE liner faced with aluminium.

Patient packs or OTC packs as appropriate

200 ml and 300 ml amber glass bottles with white plastic Jay cap closures.

500 ml amber glass bottles with white plastic screw caps with an EPE liner faced with aluminium.

6.6. Instruction for Use/Handling

No special instructions.

7. MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Limited
Hani Wells Business Park
Unit 7
Hardicker Street
Manchester
M19 2RB
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 18374/0041

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/02/2009

10 DATE OF REVISION OF THE TEXT

24/02/2009