NALISTID® SUSPENSION

(Magnesium Trisilicate 250mg, Light Magnesium Carbonate 250mg and Sodium Bicarbonate 250mg)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

R67-68 NEKEDE-NAZE
INDUSTRIAL CLUSTERS,
NEKEDE, OWERRI,
IMO STATE, NIGERIA.
TEL: +2348085784400, +2349026044603

EMAIL: info@nalispharma.com, www.nalispharma.com

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1 NAME OF THE MEDICINAL PRODUCT:

Nalistid Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Magnesium Trisilicate BP……..**..250 mg**
Light Magnesium Carbonate BP…. **250 mg**
Sodium Bicarbonate BP……..**250 mg**
Excipients……..……**q.s**

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalistid® Suspension neutralizes and counteracts the effect of hydrochloric acid in the gastric secretions. They are used in the symptomatic management of gastro intestinal disorders associated with gastric hyperacidity such as dyspepsia, abdominal pains, gastroesophageal reflux disease and peptic ulcer disease. The magnesium trislicate contained in Nalistid® is used as a food additive and as a pharmaceutical excipient, the magnesium carbonate may be used as a magnesium supplement, food additive and as a binder and diluent in tablet making while the sodium bicarbonate act as the alkalinising agent.

4.2 Posology and method of administration
For oral administration.

Dosage:
Two times daily:
6 months to 6 years - 1 teaspoonful
6 years to 12 years - 2 teaspoonfuls

4.3 Contraindications

Nalistid® Suspension is contraindicated in patients who must control sodium intake because of the presence of sodium bicarbonate (Heart failure, hypertension, renal failure, cirrhrosis, eclampsia or aldosteronism)

4.4 Special warnings and precautions for use

Nalistid® suspension containing sodium bicarbonate should not generally be given to patients with metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria. During treatment of acidosis, frequent monitoring of serum-electrolyte concentrations and acid-base status is essential. Sodium-containing salts should be given with considerable care to patients with renal impairment or aldosteronism.
Magnesium crosses the placenta. When used in pregnant women, fetal heart rate should be monitored and use within 2 hours of delivery should be avoided. Oral magnesium salts e.g. light magnesium carbonate and magnesium trisilicate should be used cautiously in patients with renal impairment. Taking with food may decrease the incidence of diarrhea. Chronic diarrhea from long-term use may result in electrolyte imbalance.

4.5 Interaction with other medicinal products

The sodium bicarbonate in raising intra-gastric pH may reduce or increase the rate and/or extent of absorption of a number of drugs. Alkalinisation of the urine leads to increased renal clearance of acidic drugs such as salicylates, tetracyclines and barbiturates. Conversely, it prolongs the half-life of basic drugs and may result in toxicity. Sodium bicarbonate enhances lithium excretion. Oral magnesium salts such as light magnesium carbonate and magnesium trisilicate decreases the absorption of tetracyclines and bisphosphonates and doses should be separated by a number of hours.

4.6 Pregnancy and lactation

Magnesium crosses the placenta. When used in pregnant women, fetal heart rate should be monitored and use within 2 hours of delivery should be avoided.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Nalistid® Suspension has a laxative effect because of the presence of magnesium salts which may cause diarrhea and hypermagnesemia in patients with renal failure due to reduced ability of the kidneys to eliminate magnesium from the body. It can also cause belching, flatulence and eructation.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium CMC, Xanthan Gum, Sorbitol, Methyl Paraben, Propyl Paraben, Polysorbate-80, Peppermint Oil, Colloidal Silicon Dioxide, Titanium Dioxide, Treated Water

6.2 Incompatibilities

None stated except as in 'Interactions with other medicaments'.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C.
Keep away from light

6.5 Nature and contents of container

200ml Pet bottles.
24 by 200ml in a carton.

6.6 Special precautions for disposal and other handling

None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

8. DRUG PRODUCT MANUFACTURER

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

9. NAFDAC REGISTRATION NUMBER(S)

A11-0843