SCHEDULING STATUS **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

INTUNGWA UMUTHI WENYONI (Suspension)

COMPOSITION: Each 5 ml contains:

Milk of magnesia 2,5 ml
Calcium carbonate 87,0 mg
Sodium citrate 62,5 mg
Alcohol content 4,8 % v/v
Preservatives: Sodium benzoate 0,1 % m/v
Methylparaben 0,1 % m/v
Propylparaben 0,01 % m/v

PHARMACOLOGICAL CLASSIFICATION:

A 11.4.1 Antacids – Acid neutralizers.

PHARMACOLOGICAL ACTION:

Antacid, with the capability of neutralizing stomach acid.

INDICATIONS:

Indicated where the use of an antacid is required.

CONTRA-INDICATIONS: Hypersensitivity to any of the ingredients. It should not be given to patients with metabolic or respiratory alkalosis, hypochlorhydria or hypocalcaemia.

WARNINGS: Do not use this product if you are on a sodium-restricted diet, or suffer from hypertension or heart failure, except under the supervision of a doctor. Do not use this product if you have kidney disease, except under the advice and supervision of a doctor. May enhance the cardiac effects of digitalis glycosides. May interfere with the absorption of other medicines given concomitantly.

DOSAGE AND DIRECTIONS FOR USE:

The following dosage may be given not more than three to four times per 24-hour period.

Children: Under 1 month: ½ medicine measure (2,5 ml)
1 – 12 months ½ to 1 medicine measure (2,5 – 5 ml)
1 - 2 years: 1 – 1½ medicine measures (5 – 7,5 ml)
3 - 5 years: 1½ - 2 medicine measures (7,5 – 10 ml)
6 – 10 years: 2 – 3 medicine measures (10 – 15 ml)

DO NOT GIVE THIS MEDICINE TO BABIES WITH A BODY MASS LESS THAN 2,5 KG. Do not use the maximum daily dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS: Calcium carbonate may cause constipation. Flatulence from released carbon dioxide is usually not serious, eructations may occur in some patients. Hypercalcaemia and alkalosis can occur following regular use of calcium carbonate. Milk-alkali syndrome has occurred, usually in patients taking high doses. Milk of magnesia may cause diarrhoea. Hypermagnesaemia may occur if renal function is impaired. The symptoms include flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. May interfere with the absorption of other medicines if taken concomitantly. May cause stomach cramps and flatulence. Excessive administration of bicarbonate-producing salts (such as sodium citrate) may lead to metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include muscle weakness, shortness of breath, restlessness, convulsions and coma. Muscle hypertonicity, twitching and tetany may develop especially in hypocalcaemic patients. Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality. Symptoms include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, fever, hypertension, tachycardia, headache, dizziness, restlessness, irritability, weakness, convulsions, coma, respiratory failure, and death. Infants may not appear to be severely dehydrated, but coma and convulsions may persist due to vascular injury. They may show respiratory distress with tachypnoea and flaring nostrils. Sodium-containing salts should be administered extremely cautiously to patients with heart failure, peripheral and pulmonary oedema, renal impairment, hypertension and pre-eclampsia. Alkalinisation of the urine by bicarbonate-producing salts leads to increased renal clearance of acidic drugs.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: See "Side-effects and Special Precautions". Consult your doctor or take the patient to the nearest hospital immediately. Treatment consists of appropriate correction of fluid and electrolyte balance. Further treatment is symptomatic and supportive.

IDENTIFICATION:

A light brown suspension with an odour of asafoetida.

PRESENTATION:

75 ml and 100 ml packed in PVC bottles.

STORAGE INSTRUCTIONS: Store below 30°C in airtight containers, protected from light. KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER: G1663 (Act 101 of 1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

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