SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

DE WITT'S ANTACID POWDER

COMPOSITION:

Each 2,5 g contains:	Sodium bicarbonate	1,2125 g
	Magnesium carbonate, light	0,25 g
	Calcium carbonate	0,5 g
	Magnesium trisilicate	0,25 g
	Aluminium hydroxide dried gel	0,05 g

PHARMACOLOGICAL CLASSIFICATION:
A 11.4.1 Antacids - Acid neutralisers

PHARMACOLOGICAL ACTION:
Antacids do not reduce the volume of hydrochloric acid secreted by the stomach, but by increasing the gastric pH, they may markedly diminish the activity of pepsin in the gastric secretion.

INDICATIONS:
Symptomatic relief of excess stomach acid, heartburn and dyspepsia.

CONTRA-INDICATIONS:
It is generally recommended that sodium bicarbonate should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

WARNINGS:
Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline.
Do not use this product if you have kidney disease, except under the advice and supervision of a doctor. 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.

DOSAGE AND DIRECTIONS FOR USE:
Powder:
Adults: One to three medicine measures (2,5 g to 7,5 g) in half a glass of water one hour after meals or as directed by a doctor. Each medicine measure contains 332 mg of sodium.
Children under 14 years: Not recommended.
Sachets:
Adults: One to three sachets (2,5 g to 7,5 g) in half a glass of water one hour after meals or as directed by a doctor. Each sachet contains 332 mg of sodium.
Children under 14 years: Not recommended.
Do not take more than 9 medicine measures (or 9 sachets) in a 24 hour period. Do not use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-Effects Aluminium Hydroxide Dried Gel: Nausea, vomiting, constipation. Large doses can cause obstruction. Excessive doses, or normal doses in patients with low phosphate diets may lead to phosphate depletion accompanied by increase resorption and urinary excretion of calcium with the risk of osteomalacia. Osteomalacia, encephalopathy and dementia have occurred in patients with chronic renal failure on high aluminium-dose as a phosphate-binding agent. It may alter the absorption of other medicines from the gastro-intestinal tract if administered concomitantly.
Side-Effects Calcium Carbonate: May cause constipation. Flatulence from carbon dioxide release 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.
Side-Effects Magnesium Carbonate and Magnesium Trisilicate: May cause diarrhoea. Release of carbon dioxide may cause discomfort. Hypermagneseamia may occur if renal function is impaired. May interfere with absorption of other medicines if taken concomitantly.
Side-Effects Sodium Bicarbonate: Can cause stomach cramps and flatulence.

Special Precautions:
Use with care in patients with renal failure.
May enhance the cardiac effects of digitalis glycosides.
May interfere with the absorption of other medicines given concomitantly.
Should be administered with extreme caution to patients with congestive heart failure, renal impairment, cirrhosis of the liver or hypertension and to patients receiving corticosteroids. Alkalinisation of the urine by sodium bicarbonate leads to increase in renal clearance of acidic drugs.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "Side-effects and Special Precautions".
Symptoms may include shortness of breath, muscle weakness (associated with potassium depletion) and mental disturbance such as restlessness, convulsions and coma. Muscle hypertonicity, twitching and tetany may develop especially in hypocalcaemic patients due to increased protein binding and renal reabsorption of calcium.
Excessive doses may also lead to sodium overloading and hyperosmolality, the most serious effect of which is dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage. Treatment consists mainly of appropriate correction of the fluid and electrolyte balance. Replacement of calcium ions may be of particular importance. Further treatment is symptomatic and supportive.

IDENTIFICATION:
A smooth white powder with a pleasant peppermint odour and a saline taste.

PRESENTATION:
100g and 200g tinplate containers
20 or 30 x 2,5 g foil sachets in printed unit cartons.

STORAGE INSTRUCTIONS:
Store in a dry place below 25°C .
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER: E/11.4.1/731

NAME AND BUSINESS ADDRESS OF APPLICANT:
GULF DRUG COMPANY (PTY) LTD
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