SCHEDULING STATUS: **S0**

PROPRIETARY NAME **MUTHI WENYONI ANTACID**

(AND DOSAGE FORM): **MIXTURE**

COMPOSITION:

Each 5 ml contains:

Calcium carbonate	87 mg
Light magnesium carbonate	87 mg
Sodium bicarbonate	87 mg
Sodium citrate	62 mg
Preservative: Propylparaben	0,15 % m/v

Contains sugar: Sucrose 1,1 g

PHARMACOLOGICAL CLASSIFICATION:

A 11.4.1 Antacids - Acid neutralizers

PHARMACOLOGICAL ACTION:

Antacid, with the capability of neutralizing the acid in the stomach.

Pharmacokinetics / Pharmacodynamics:

Carbonates:

Absorption: Calcium **[**containing antacids**]**: approximately 15 % of the calcium in calcium carbonate is absorbed from the intestine in normal persons. **[**The amount of calcium absorbed from the gastrointestinal tract is determined by hormonal factors, particularly parathyroid hormone, and vitamin D.

Onset and duration of action: Onset of action is dependent upon the ability of the antacid to solubilize in the stomach and react with the hydrochloric acid. Duration of action is determined primarily by gastric emptying time. Depending on the kind of antacid used, the duration of action in fasting patients may range from 20 to 60

Clinical Committee recommendations on package insert– See Reference 1.

minutes.

However, when the antacid is given 1 hour after meals, the acid neutralising effect may be prolonged up to 3 hours. Calcium carbonate has been shown to have a fast onset of action and a prolonged duration of action. Magnesium carbonate has an intermediate onset of action and a short duration of action.

Calcium carbonate is converted to calcium chloride by gastric acid.**]**

Elimination: Renal and fecal. **[**15 to 30% of the salts formed are absorbed and are then excreted by the kidneys.**]**

Citrates:

[They undergo biotransformation where they are oxidised in the body to form potassium bicarbonate or sodium bicarbonate. Effects are essentially those of chlorides before absorption and those of bicarbonates after absorption.**]**

Elimination: Urinary. **[**less than 5 % is unchanged**]**

Bicarbonates:

[Administration of bicarbonates, such as**]** Sodium bicarbonate, by mouth causes neutralisation of gastric acid. **[**with the production of carbon dioxide. Bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine, which is rendered alkaline, and there is an accompanying diuresis.**]** Sodium bicarbonate has a fast onset of action and a short duration of action.

Elimination - Sodium bicarbonate: Renal. **[**CO2 formed is eliminated via lungs.**]**

INDICATIONS:

Where the use of an antacid is indicated.

CONTRA-INDICATIONS:

Sensitivity to any of the ingredients. It should not be administered to patients with

Wording changed according to Clinical Committee recommendations on

metabolic or respiratory alkalosis, hypercalcaemia, or hypochlorhydria.

package insert– See Reference 1.

WARNINGS:

Contains 19,5 mg and 39 mg of sodium in **[**½ and 1**]** 2,5 ml and 5 ml medicine measure respectively.

Clinical Committee recommendations on package insert– See Reference 1.

This product must not be used in persons who are on a sodium-restricted diet, or suffer from hypertension, or heart failure, except under the supervision of a doctor.

Use with care in patients with renal failure.

INTERACTIONS:

This product may enhance the cardiac effects of digitalis glycosides.

Magnesium carbonate may interfere with the absorption of other medicines given concomitantly.

Sodium bicarbonate should be administered with extreme caution to patients receiving corticosteroids.

Alkalinization of the urine by sodium bicarbonate leads to an increase in renal clearance of acidic drugs.

PREGNANCY AND LACTATION:

Pregnancy

[Antacids are generally considered safe as long as chronic high doses are avoided.**]**

Clinical Committee recommendations on package insert– See Reference 1.

Aluminium-, calcium-, or magnesium-containing antacids – Adequate and well-controlled studies in humans have not been done; however, there have been reports of antacids causing such adverse effects as hypercalcaemia, hypomagnesaemia, hypermagnesaemia, and increased tendon reflexes in foetuses and/or neonates whose mothers were chronic users of these antacids, especially in high doses. **[**Studies have not been done in animals.

Sodium bicarbonate-containing antacids – Problems in humans have not been

documented; however, risk-benefit must be considered because sodium bicarbonate is absorbed systemically. Chronic use may lead to systemic alkalosis. The sodium load that is absorbed can also cause oedema and weight gain.**]**

Lactation

[Problems in humans have not been documented; although**]** Some aluminium-, calcium-, and magnesium may be distributed into breast milk. **[**the concentration is not great enough to produce an effect in the neonate.**]**

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)
1month - under 1 year:	½ - 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:

Gastrointestinal disorders:

The following side effects have been reported but the frequency is unknown:

Constipation, flatulence, diarrhoea, abdominal discomfort, stomach cramps.

Metabolism and nutrition disorders:

Side-effects section organized as per MedDRA system organ class classification and as per CIOMS classification.

Martindale 34th Edition, pages 1254,1272,1223. See

The following side effects have been reported but the frequency is unknown:

Hypercalcaemia, alkalosis.

Less frequent: Milk-alkali syndrome.

Hypermagnesaemia (if renal function is impaired): *The following side effects have been reported but the frequency is unknown*:

Vascular disorders: Flushing of the skin, hypotension due to peripheral vasodilatation.

Metabolism and nutrition disorders: Thirst.

Nervous system disorders: Drowsiness, loss of tendon reflexes due to neuromuscular blockade, muscular weakness, coma.

Psychiatric disorders: Confusion.

Respiratory, thoracic and mediastinal disorders: Respiratory depression.

Cardiac disorders: Cardiac arrythmias, cardiac arrest.

Musculoskeletal and connective tissue disorder:

The following side effects have been reported but the frequency is unknown:

Muscle hypertonicity, twitching, and tetany (only in hypocalcaemic patients with excessive bicarbonate administration).

See also under heading “Known symptoms of overdosage and particulars of its treatment”.

Special Precautions:

Sodium bicarbonate should be administered with extreme caution to patients with congestive heart failure, renal impairment, cirrhosis of the liver or hypertension.

Overdose: Excessive doses may also lead to sodium overloading and hyperosmolality. Symptoms include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death. Infants may appear not to be severely

Reference 2.

USPDI (25th edition), pages 217-218. See Reference 3.

Retained under “Special Precautions” and separated as per Clinical Committee recommendations on package insert– See Reference 1.

dehydrated, but coma and convulsions may persist due to vascular injury. They may show respiratory distress with tachypnoea and flaring nostrils.

Excessive dosing: Excessive administration of sodium bicarbonate may lead to metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include shortness of breath, muscle weakness (associated with potassium depletion), and mental disturbances 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 oral administration of citrate salts may have a laxative effect.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment consists of appropriate correction of fluid and electrolyte balance. Further treatment is symptomatic and supportive. Consult your doctor or take the patient to the nearest hospital.

Clinical Committee recommendations on package insert– See Reference 1.

IDENTIFICATION:

A well-shaken mixture is pale-orange in colour. It has an odour and taste of asafoetida. On standing an off-white sediment separates leaving a clear orange-brown layer. A well-shaken sample is opaque.

PRESENTATION:

75 ml and 100 ml packed in clear PVC bottles.

STORAGE INSTRUCTIONS:

Store at or below 30 ºC in airtight containers and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/11.4.1/650

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE

OF REGISTRATION:

Tiger Consumer Brands

2 Purlin Street

Isando

Kempton Park

1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

To be allocated.

REFERENCES

No.	References
1	**MUTHI WENYONI ANTACID** MIXTURE package insert with Clinical Committee recommendations.
2	Martindale 34th Edition, pages 1254,1272,1223.
3	USPDI (25th edition), pages 217-218.