1.3.1.1 CURRENT APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

UMTHUTHUZELI 131,37 mg Mixture

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Sodium bicarbonate 131,37 mg

Ethyl alcohol (96 %) 5,22 % *v/v*

Preservative:

Methyl hydroxybenzoate 0,1 % *m/v*

Contains sugar: Sucrose 2,96 g

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Mixture

Bright, dark brown mixture.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

UMTHUTHUZELI is indicated for winds, gripes, colic and upset stomach associated with excess acid in infants.

4.2 Posology and method of administration

Posology

SHAKE THE BOTTLE BEFORE USE.

Infants:

5 ml (one medicine measure) after meals or as required.

UMTHUTHUZELI should not be taken for longer than a few days without medical advice.

Method of administration

For oral use only.

4.3 Contraindications

UMTHUTHUZELI is contraindicated in:

- patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.
- patients who are hypersensitive to sodium bicarbonate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

UMTHUTHUZELI should be used extremely cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral or pulmonary oedema, or aldosteronism.

Care should be taken to avoid excessive use in infants.

Special care must be taken when administering UMTHUTHUZELI with other medicines, and in particular with salicylates, tetracyclines, barbiturates and lithium. (Refer to section 4.5).

UMTHUTHUZELI contains a high percentage of alcohol.

4.5 Interactions with other medicinal products and other forms of interaction

Bicarbonate may reduce or increase the rate and/or extent of absorption of a number of medicines due to raising intra-gastric pH. Alkalinisation of the urine leads to increased renal clearance of acidic medicine such as salicylates, tetracyclines and barbiturates.

Conversely, it may prolong the half-life of alkaline medicines and result in toxicity.

Sodium bicarbonate enhances the excretion of lithium. (Refer to section 4.4).

4.6 Fertility, pregnancy and lactation

Not applicable. UMTHUTHUZELI is not intended for administration to women of child-bearing age.

4.7 Effects on ability to drive and use machines

Not applicable. UMTHUTHUZELI is intended for use by infants only.

4.8 Undesirable effects

The following side effects may occur:

Gastrointestinal disorders

Frequency unknown: Stomach cramps, flatulence, belching, flatulence

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Excessive use of UMTHUTHUZELI may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients. Treatment of metabolic alkalosis and hypernatraemia associated with sodium bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte

balance. Replacement of calcium, chloride and potassium ions may be of particular importance.

Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality.

Sodium "excess" may take two forms. The first is a rise in extracellular concentration (hypernatraemia) and the second form is too much sodium and water in the body without change in extracellular concentration.

Symptoms of hypernatraemia may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Symptoms of hyponatraemia may include anorexia, fatigue, muscle weakness, diarrhoea, abdominal cramps, confusion, hypotension, tachycardia, weakened pulse, cyanosis, hypothermia, pitting oedema, oliguria and convulsions.

Treat symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

11.4.3 Medicines acting on the gastro-intestinal tract: Others.

Pharmacotherapeutic group: Antacids with sodium bicarbonate

ATC code: A02AH

Sodium bicarbonate is an antacid that neutralises acid secretions in the gastrointestinal tract.

5.2 Pharmacokinetic properties

Sodium bicarbonate neutralises gastric acid secretions with the production of carbon dioxide. Bicarbonate not involved in neutralising gastric acid is absorbed and in the absence of a deficit of bicarbonate in the plasma, the

bicarbonate ions are then excreted in the urine rendering it alkaline, and there is an accompanying diuresis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aniseed oil

Caramel

EFM compound rhubarb tincture

Ethyl alcohol (96 %)

Glycerol

Methyl hydroxybenzoate

Purified water

Sucrose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep bottle tightly closed and protect from light.

Keep bottle in outer carton until prior to use.

Store at or below 25 °C.

6.5 Nature and contents of container

50 ml and 100 ml amber plastic bottles with a white aluminium cap, contained in an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Avid Brands S.A. (Pty) Ltd

Suite 9, Hillcrest Office Park

2 Old Main Road

Hillcrest

3610

8. REGISTRATION NUMBER

E/11.4.1/1542

9. DATE OF FIRST AUTHORISATION

12 January 1994

10. DATE OF REVISION OF THE TEXT

05 September 2022