1.5.5.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

GR BABIES STOMACH MIXTURE, Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Magnesium carbonate light	0,160 g
Sodium bicarbonate	0,080 g
Ethyl alcohol	8,24 % *v/v*
Preservative:	
Chloroform	0,50 % *v/v*

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Suspension

A white suspension with a peppermint flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GR BABIES STOMACH MIXTURE is indicated for use as an antacid.

4.2 Posology and method of administration

Posology:

Give three to four times a day.

Paediatric population

Under 1 month: 2,5 ml (½ medicine measure).

1 - 6 months: 2,5 – 5 ml (½ - 1 medicine measure).

6 - 12 months: 5 ml (1 medicine measure).

1 - 2 years: 5 - 7,5 ml (1 - 1½ medicine measures).

3 - 5 years: 7,5 - 10 ml (1½ – 2 medicine measures).

6 - 10 years 10 - 15 ml (2 - 3 medicine measures).

Do not give this medicine to babies with a body mass less than 2,5 kg

DO NOT USE THE MAXIMUM DOSAGE OF THIS PRODUCT FOR MORE THAN TWO WEEKS, EXCEPT ON THE ADVICE, AND UNDER THE SUPERVISION, OF A DOCTOR.

SHAKE THE BOTTLE BEFORE USE.

Method of administration:

For oral use only.

4.3 Contraindications

GR BABIES STOMACH MIXTURE is contraindicated in:

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

4.4 Special warnings and precautions for use

GR BABIES STOMACH MIXTURE should be given extremely cautiously to patients with congestive heart failure, oedema, renal impairment, cirrhosis of the liver, hypertension, eclampsia, aldosteronism, or to patients receiving corticosteroids.

Care should be taken to avoid excessive use in infants.

Special care must be taken when administering GR BABIES STOMACH MIXTURE with other medicines, and in particular with salicylates, tetracyclines, barbiturates, bisphosphonates and lithium. Refer to section 4.5.

This product contains a high percentage of alcohol. Refer to section 2

4.5 Interaction with other medicines 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.

Magnesium salts may decrease the absorption of tetracyclines and bisphosphonates, and doses should be separated by a number of hours. Refer to section 4.4

4.6 Fertility, pregnancy and lactation

GR BABIES STOMACH MIXTURE is not intended for administration to women of child-bearing age.

4.7 Effects on ability to drive and use machines

Not relevant as GR BABIES STOMACH MIXTURE is indicated for infants only.

4.8 Undesirable effects

Metabolism and nutrition disorders

Frequency unknown: Hypermagnesaemia and metabolic alkalosis.

Gastrointestinal disorders

Frequency unknown: Stomach cramps, belching, flatulence, gastrointestinal irritation and watery diarrhoea.

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 GR BABIES STOMACH MIXTURE 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.

Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality. Hypermagnesaemia may occur in patients with impaired renal function taking large amounts of magnesium. Symptoms include nausea, vomiting, CNS and respiratory depression, hyporeflexia, muscle weakness and cardiovascular effects including peripheral vasodilation, hypotension bradycardia and cardiac arrest.

Treatment of overdose

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.

Treatment of mild hypermagnesaemia is usually limited to restricting magnesium intake.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids, ATC code: A02AH

Sodium bicarbonate and magnesium carbonate are antacids that neutralises acid secretions in the gastrointestinal tract.

5.2 Pharmacokinetic properties

Sodium bicarbonate and magnesium carbonate neutralise 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.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peppermint oil

Purified water

Contains Alcohol: Ethyl alcohol 8,24 % *v/v*

Preservative: Chloroform 0,50 % *v/v*

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a well closed container at or below 25°C.

DO NOT KEEP OR USE OUTDATED MEDICINES.

6.5 Nature and contents of container

100 ml clear PVC bottle with a 24 mm white aluminium cap with a white, expanded polyethylene liner, contained in an outer carton.

Not all pack sizes may be marketed.

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

E1135

9. DATE OF FIRST AUTHORISATION

12 November 1993

10. DATE OF REVISION OF THE TEXT

21 January 2022