

1.3.2 CURRENT APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GR BABIES STOMACH MIXTURE

Magnesium carbonate light 0,160 g and sodium bicarbonate 0,080 g per 5 ml suspension.

Read all of this leaflet carefully because it contains important information for you

GR BABIES STOMACH MIXTURE is available without a doctor's prescription, for you

to treat a mild illness. Nevertheless, you still need to use GR BABIES STOMACH

MIXTURE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GR BABIES STOMACH MIXTURE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What GR BABIES STOMACH MIXTURE is and what it is used for
2. What you need to know before you use GR BABIES STOMACH MIXTURE
3. How to use GR BABIES STOMACH MIXTURE
4. Possible side effects
5. How to store GR BABIES STOMACH MIXTURE
6. Contents of the pack and other information

1. What GR BABIES STOMACH MIXTURE is and what it is used for

GR BABIES STOMACH MIXTURE is an antacid which neutralises stomach acid.

2. What you need to know before you give GR BABIES STOMACH MIXTURE

Do not administer GR BABIES STOMACH MIXTURE:

- If your infant has:

- blood pH higher than normal,
 - low calcium levels,
 - low stomach acid.
- if your infant is hypersensitive (allergic) to magnesium carbonate, sodium bicarbonate or any of the ingredients of GR BABIES STOMACH MIXTURE (listed in section 6).

Warnings and precautions

Take special care with GR BABIES STOMACH MIXTURE:

- If your infant has heart failure, swelling, reduced kidney function, high blood pressure, or high levels of aldosterone (steroid hormone) extreme caution is advised.
- Special care must be taken when administering GR BABIES STOMACH MIXTURE with other medicines, and in particular with salicylates, tetracyclines, barbiturates, bisphosphonates and lithium.

Children

- GR BABIES STOMACH MIXTURE contains a high percentage of alcohol.

Other medicines and GR BABIES STOMACH MIXTURE

Always tell your health care provider if you are administering any other medicine.

(This includes all complementary or traditional medicines.)

GR BABIES STOMACH MIXTURE may interact with a number of medicines.

GR BABIES STOMACH MIXTURE may:

- decrease or increase the absorption of other medicines due to raising stomach pH
- increase excretion through the kidneys of lithium and acidic medicines such as salicylates, tetracyclines and barbiturates
- delay the excretion of certain medicines and result in toxicity.
- decrease absorption of tetracyclines and bisphosphonates.

Using GR BABIES STOMACH MIXTURE with food, drink and alcohol:

Alcohol should not be consumed when using GR BABIES STOMACH MIXTURE as it has a high alcohol content. Do not use GR BABIES STOMACH MIXTURE with other medicines containing alcohol.

GR BABIES STOMACH MIXTURE is normally given between meals.

Pregnancy and breastfeeding:

Not applicable since GR BABIES STOMACH MIXTURE is not intended for use by women of child-bearing age.

Driving and using machines

Not applicable as GR BABIES STOMACH MIXTURE is intended for use by infants only.

GR BABIES STOMACH MIXTURE contains chloroform 0,50 % v/v, ethyl alcohol 8,24 % v/v, peppermint oil and purified water

Contains a high percentage of alcohol.

3. How to administer GR BABIES STOMACH MIXTURE

Do not share medicines prescribed for your infant with any other person.

Give three to four times a day.

CHILDREN:

Under 1 month: 2,5 ml ($\frac{1}{2}$ medicine measure).

1 - 6 months: 2,5 – 5 ml ($\frac{1}{2}$ - 1 medicine measure).

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

1 - 2 years: 5 - 7,5 ml (1 - $1\frac{1}{2}$ medicine measures).

3 - 5 years: 7,5 - 10 ml ($1\frac{1}{2}$ – 2 medicine measures).

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

Do not give this medicine to babies with a bodymass 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.

Always give GR BABIES STOMACH MIXTURE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

If you administer more GR BABIES STOMACH MIXTURE than you should:

Symptoms of overdosage may include mood changes, tiredness, slow breathing, muscle weakness or muscle twitching, irregular heartbeat, fever or sweating, nausea and vomiting.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed administering a dose of GR BABIES STOMACH MIXTURE:

Skip the missed dose and continue with the next dose as directed.

Do not double the dose.

4. Possible side effects

GR BABIES STOMACH MIXTURE can have side effects.

Not all side effects reported for GR BABIES STOMACH MIXTURE are included in this leaflet.

Should your infant or child's general health worsen or if your infant or child experiences any untoward effects while taking GR BABIES STOMACH MIXTURE, please consult your healthcare provider for advice.

The following side effects may occur:

Frequency unknown: Stomach cramps, burping, flatulence (gassiness), stomach irritation, watery diarrhoea, high magnesium blood levels and increased tissue pH.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found

online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of

GR BABIES STOMACH MIXTURE.

5. How to store GR BABIES STOMACH MIXTURE.

- Store at or below 25 °C.
- Keep the bottle tightly closed.
- Keep bottle in unit carton until prior to use.
- Do not use after the expiry date stated on the label.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What GR BABIES STOMACH MIXTURE contains

- The active substances are 0,160 g magnesium carbonate light and 0,080 g sodium bicarbonate per 5 ml suspension.
- The other ingredients are chloroform 0,50 % v/v (as preservative), ethyl alcohol 8,24 % v/v, peppermint oil and purified water.

What GR BABIES STOMACH MIXTURE looks like and contents of the pack

GR BABIES STOMACH MIXTURE is a white suspension with a peppermint flavour, supplied in plastic amber bottles of 100 ml with a white aluminium cap with a white liner, contained in an outer carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

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