Patient Information Leaflet for Medicines for Human Use:

MAGASIL Mixture

SCHEDULING STATUS: S0

MAGASIL Mixture

Magnesium carbonate, light

Magnesium trisilicate

Sodium bicarbonate

Preservatives:

Chloroform 0,17 % *v/v*

Alcohol content:

Ethanol 1,45 % *v/v*

Sugar free.

Contains sweeteners:

Sodium cyclamate 36 mg per 10 mL

Sodium saccharin 4 mg per 10 mL

Sodium content: 141,4 mg/10 mL

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

MAGASIL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MAGASIL carefully to get the best results from it**.**

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

What is in this leaflet

1. What MAGASIL is and what it is used for

2. What you need to know before you take MAGASIL

3. How to take MAGASIL

4. Possible side effects

5. How to store MAGASIL

6. Contents of the pack and other information

1. What MAGASIL is and what it is used for

MAGASIL contains the active substances light magnesium carbonate, magnesium trisilicate and sodium bicarbonate with all three ingredients being antacids, which has the capability of neutralising acid in the stomach. MAGASIL also has mild laxative action that gently encourage bowel movements without causing strong or sudden purging.

MAGASIL is used for the relief of:

- Burning of the upper gastrointestinal tract tissues, caused by intake of corrosive chemicals such as acids.
- Indigestion felt as a burning sensation in the chest (heartburn), when stomach acid and sometimes food flow backward from the stomach into the oesophagus (the elongated tubular organ that food travels through to reach the stomach for further digestion).
- A condition where the stomach produces excessive amounts of hydrochloric acid (hyperacidity). This excess acid can lead to discomfort, pain, and various digestive issues,
- Discomfort or pain in the upper abdomen, often experienced after eating or drinking (dyspepsia or indigestion),
- Inflammation of the stomach lining (gastritis)
- A condition where the lining of the oesophagus becomes inflamed or damaged due to stomach acid flowing back up into it (reflux oesophagitis).

2. What you need to know before taking MAGASIL

Do not take MAGASIL:

- If you are hypersensitive (allergic) to light magnesium carbonate, magnesium trisilicate and sodium bicarbonate, or to any of the other ingredients of MAGASIL (listed in section 6).
- If you have severe kidney failure.
- If you have low levels of calcium or phosphate in your blood.
- If you are on a low salt (sodium) diet.
- If you have heart failure.
- If you have high blood pressure.
- If you have liver problems.
- If you have high levels of alkali in the blood.
- If you have reduced stomach acid.

Warnings and precautions

Take special care with MAGASIL:

- If you have problems with excess fluid buildup in body tissues (water retention), especially if you
  - have kidney problems,
  - are taking steroids,
  - have a condition where the blood and body fluids become too acidic due to the lungs' inability to remove enough carbon dioxide (CO2),
  - are pregnant and have eclampsia - a condition in which one or more convulsions occur due to very high blood pressure, often followed by coma and posing a threat to the health of mother and baby,
  - have aldosteronism - a condition in which there is excessive secretion of aldosterone, which disturbs the balance of sodium, potassium, and water in the blood and so leads to high blood pressure.

- If you have kidney problems, you may develop a condition where there is an abnormally high level of magnesium in the blood (hypermagnesaemia). Symptoms can range from mild, such as nausea and muscle weakness, to severe, including respiratory depression, cardiac arrest, and even coma.
- If you have a condition where the pH of the body's fluids becomes too alkaline/is elevated (metabolic alkalosis) or low levels of potassium (hypokalaemia) in the blood. Symptoms can range from mood changes, restlessness, tiredness, shortness of breath to irregular heartbeat, convulsions and coma.
- If you have low levels of calcium in your blood (hypocalcaemia), you may develop twitching or involuntary muscle spasms, cramps, and contractions or stiff muscles resistant to stretching, making it difficult to move normally.
- If you have problems in your digestive tract, such as stomach cramps, farting or diarrhoea as MAGASIL may make this worse.
- If you have kidney stones as overuse of MAGASIL may aggravate this condition.

Children and adolescents

For use in adults only.

Other medicines and MAGASIL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- The active ingredients in MAGASIL can prevent the absorption of some medicines from your gut or change the elimination from your body to make their effect weaker. If you are unsure, please speak to your pharmacist about this.
    - ACE inhibitors for high blood pressure.
    - Aspirin (used to reduce pain, fever, and inflammation, and to prevent blood clots).

- Medicines for bacterial infections (e.g. azithromycin, cephalosporins, fluoroquinolones, isoniazid, methenamine, nitrofurantoin, rifampicin, tetracyclines), fungal infections (e.g. itraconazole, ketoconazole) or viral infections (e.g. atazanavir, tipranavir).
- Medicines to prevent blood clotting (e.g. dipyridamole).
- Medicines for mental illness such as mania, depression, schizophrenia, anxiety, insomnia (e.g. barbiturates, phenothiazines, sulpiride, lithium).
- Gabapentin or phenytoin (for epilepsy).
- Chloroquine, hydroxychloroquine or proguanil to prevent or treat malaria.
- Bisphosphonates for osteoporosis.
- Fexofenadine (an antihistamine).
- Deflazacort (a corticosteroid).
- Lansoprazole (for a stomach ulcer).
- Rosuvastatin (for high cholesterol).
- Levothyroxine (for thyroid problems).
- Penicillamine (for rheumatoid arthritis).
- Digoxin (for heart failure).
- Ulipristal (morning after pill).
- Mycophenolate (an immunosuppressant medicine).
- Eltrombopag to treat low platelet counts.
- Erlotinib (a cancer medicine).
- Bile acids (used to aid in the digestion and absorption of fats and fat-soluble vitamins in the small intestine).
- Iron preparations (used to treat iron-deficiency anaemia).
- Polystyrene sulphonate resins (used to remove excess amounts of potassium from the body).

MAGASIL may affect the action of these and other medicines, so allow 2 to 4 hours between taking this and any other medicine.

MAGASIL with food, drink and alcohol

No available data.

Pregnancy and breastfeeding

You should not receive MAGASIL while you are pregnant or breastfeeding your baby as the safety of MAGASIL during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while receiving MAGASIL, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Driving and using machines

MAGASIL should have no or negligible influence on the ability to drive and use machines. Do not drive or operate machinery until you are aware of the measure to which MAGASIL affects you.

Excipient warnings

MAGASIL contains sodium

MAGASIL contains 141,4 mg sodium (main component of cooking/table salt) in each 10 mL dose.

This is equivalent to 7,1 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need six or more 5 mL medicine measures daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

MAGASIL contains alcohol

This medicine contains 0,116 mg of alcohol (ethanol) in each 10 mL of mixture. The amount in 10 mL of this medicine is equivalent to 29 mL beer or 11,6 mL wine. The small amount of alcohol in this medicine is not likely to have any noticeable effects on adults.

3. How to take MAGASIL

Always take MAGASIL exactly as described in the leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

General information

For use in adults only.

If the symptoms continue for longer than 2 weeks or if your condition gets worse, do not continue to take MAGASIL, and consult your doctor immediately.

The usual dose is:

Adults

Two to four medicine measures (10 mL to 20 mL) every four hours.

Method of administration

MAGASIL must be taken orally. REMEMBER TO SHAKE THE BOTTLE BEFORE USING THE MEDICINE.

If you have the impression that the effect of MAGASIL is too strong or too weak, tell your doctor or pharmacist.

If you take more MAGASIL than you should

Overuse of MAGASIL with large doses and use for a long time, may cause changes in your blood mineral levels such as high magnesium (hypermagnesaemia) or low potassium

(hypokalaemia) or a condition where the pH of the body's fluids becomes too alkaline (pH is elevated) (metabolic alkalosis). Please see section 2 “Warnings and precautions” for signs and symptoms of these conditions.

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

If you forget to take MAGASIL

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

MAGASIL can have side effects.

Not all side effects reported for MAGASIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MAGASIL, please consult your healthcare provider for advice.

Tell your doctor if you notice any of the following:

Side effects occurring with frequency unknown

- Hypermagnesemia (excess amount of magnesium in the blood). Hypermagnesemia may present with the following symptoms; heart attack, irregular heartbeat, coma, flushing of the skin, loss of tendon reflexes, muscle weakness, slow and ineffective breathing.
- Hypokalaemia (low potassium in the blood) or metabolic alkalosis (a condition where the pH of the body's fluids becomes too alkaline/is elevated). Please see section 2 “Warnings and precautions” for signs and symptoms of these conditions.
- Diarrhoea.
- Stomach cramps.
- An increase in the amount of air/gas in the stomach (flatulence).

- Twitching or involuntary muscle spasms, cramps, and contractions.
- Stiff muscles resistant to stretching, making it difficult to move normally.
- Kidney stones (see section 2 “Warnings and precautions”).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MAGASIL.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

5. How to store MAGASIL

Store all medicines out of reach of children.

- Store in a cool, dark place at or below 25 °C.
- Do not use after the expiry date stated on the bottle label/unit carton/foil.

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 MAGASIL contains

- The active substances are light magnesium carbonate, magnesium trisilicate and sodium bicarbonate.

- There other ingredients are:

  Chloroform

  Chloroform spirit

  Peppermint flavour FLV6147ZA

  Purified water

  Sodium cyclamate

  Sodium saccharin

  Xanthan gum.

What MAGASIL looks like and contents of the pack

MAGASIL is a white homogenous mixture with peppermint odour and taste and is presented in:

- 100 mL, 200 mL and 500 mL amber PVC bottles with white LDPE snap-on caps and 2,5 L amber HDPE containers with white LDPE caps.
- 100 mL and 200 mL white HDPE bottles with white LDPE flip-top cap.
- Foil sachets containing 10 mL packed in a printed outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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