PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GELUSIL-S, 200 mg, 200 mg, 20 mg, tablets

Aluminium hydroxide dried gel, magnesium hydroxide and simethicone (activated methylpolysiloxane)

Contains sugar (confectioners' sugar 584,0 mg per tablet) and mannitol 120 mg per tablet

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

GELUSIL-S is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GELUSIL-S carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GELUSIL-S 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.

What is in this leaflet

1. What GELUSIL-S is and what it is used for

2. What you need to know before you take GELUSIL-S

3. How to take GELUSIL-S

4. Possible side effects

5. How to store GELUSIL-S

6. Contents of the pack and other information

1. What GELUSIL-S is and what it is used for

GELUSIL-S belongs to a group of medicines called antacids.

GELUSIL-S is used:

- for the relief of dyspepsia (indigestion)

- for heartburn, bloating or flatulence (excessive gas)
- in the management of stomach ulcers, as an adjunctive treatment.

2. What you need to know before you take GELUSIL-S

Do not take GELUSIL-S:

- if you are hypersensitive (allergic) to aluminium hydroxide, magnesium, simethicone or any of the other ingredients of GELUSIL-S (listed in section 6).
- if you have kidney failure (swelling of legs, ankles and feet), and if you have impaired kidney function (you don't pass or pass very little urine per day).
- if you are debilitated (feeling very weak and have no energy).
- GELUSIL-S should not be given to children (see section 3).

Warnings and precautions

- if you are on a low phosphorous diet as the use of GELUSIL-S may lead to the softening of your bones (osteomalacia)
- if you have porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin) and are undergoing haemodialysis
- high doses of GELUSIL-S may trigger or aggravate intestinal obstruction with symptoms such as cramping abdominal pain, nausea, constipation
- if you have kidney problems as long term exposure may lead to the loss of your ability to think and reason or a blood disorder called microcytic anaemia
- high doses of GELUSIL-S may cause diarrhoea and hypermagnesaemia (a condition in which there is a high level of magnesium in the blood) in people with kidney problems
- if you are an elderly patient

Your doctor may request tests to monitor your condition before or during treatment.

Other medicines and GELUSIL-S

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Do not take any other oral medication within at least 2 hours of taking GELUSIL-S.

GELUSIL-S may reduce the absorption of the following medicines:

- Certain antibiotics (such as oral tetracyclines, rifampicin, ciprofloxacin, cefdinir, cefpodoxime, methenamine, fluroquinolones, lincosamides).
- Certain anti-fungal medicines (such as ketoconazole).
- Medicines called quinines used in the prevention of malaria and treatment of rheumatoid arthritis (such as hydroxychloroquine, chloroquine).
- Medicines used to treat some bone disorders such as bisphosphonates.
- Medicines that alter the heart rate (such as digoxin or quinidine, atenolol, metoprolol).
- Certain medicines used to treat mental conditions (such as chlorpromazine).
- Certain medicines used to treat an underactive thyroid (such as levothyroxine) as the effect of these medicines may be reduced by GELUSIL-S.
- Medicines used to treat high levels of potassium in your blood (such as polystyrene sulphonate) as the effect of these medicines may be reduced by GELUSIL-S.
- Vitamins, as the effect of vitamins may be reduced.
- Medicines used to treat tuberculosis (isoniazid, rifampicin).
- Other medicine used to reduce the stomach acid called H_2 antagonists.
- Phenytoin used to treat epilepsy.
- Oral iron preparations which are used to prevent and treat iron deficiency.
- Medicines that are used to block involuntary muscle movements.
- Sedatives and sleep-inducing medicines made of barbituric acid.
- Medicines that contain warfarin which are used to reduce the formation of blood clots.
- Medicines used to treat active duodenal ulcers such as sucralfate.

- Medicines containing the chemical sodium fluoride which are used to prevent dental cavities.
- Medicines used to treat schizophrenia (such as phenothiazine).
- Medicines used to treat pain such as diflunisal and indomethacin.
- Medicines used to treat joint pains and abnormal chemical reactions in the body such as penicillamine.
- Medicines containing rosuvastatin used to prevent heart diseases and lower cholesterol made by the liver.
- Salicylates including aspirin.

Medicines which may result in increased aluminium levels in the blood include:

- Antacids and ulcer medication, especially in people who suffer from kidney problems.

GELUSIL-S with food and drink

GELUSIL-S must preferably be taken between meals.

Pregnancy, breastfeeding and fertility

Safe use of GELUSIL-S during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking GELUSIL-S.

Driving and using machines

GELUSIL-S should not impair your ability to drive or operate heavy machines.

GELUSIL-S contains sugar (confectioners' sugar 584,0 mg per tablet)

GELUSIL-S contains confectioners' sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GELUSIL-S.

May be harmful to the teeth.

3. How to take GELUSIL-S

Do not share medicines prescribed for you with any other person.

Always take GELUSIL-S exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

Adults (including the elderly):

The usual dosage is one or two tablets chewed or allowed to dissolve in the mouth 4 to 8 times a day, preferably between meals, or as directed by a doctor or pharmacist.

Do not take more than 16 tablets in a 24 hour period.

Do not use the maximum dosage of GELUSIL-S for more than 2 weeks, except under the advice or supervision of a doctor.

Children:

Not recommended for use in children.

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

If you take more GELUSIL-S than you should

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

Symptoms of overdose may include diarrhoea, abdominal pain, vomiting.

If you forget to take a dose of GELUSIL-S

If you forget to take a dose of GELUSIL-S, take the missed dose as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

4. Possible side effects

GELUSIL-S can have side effects.

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

If any of the following happens, stop taking GELUSIL-S and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to GELUSIL-S. You may need serious medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- hypermagnesaemia: a condition where there is an unusually high level of magnesium in your body (you may experience flushing of the skin, thirst, feeling dizzy or light-headed, drowsiness, confusion, muscle weakness or tightness, breathing problems, fast or irregular heartbeat)
- discomfort or pain in your chest, shortness of breath as these may be symptoms of a heart attack
- irregular heart beat (cardiac dysrhythmias), coma
- difficulty in breathing
- difficulty focusing, memory loss, trouble with problem-solving skills (possible signs of brain disease)
- low blood pressure (feeling dizzy)
- abnormal kidney function such as less urine than normal, fatigue and weakness
- bone pain, bones that fracture easily (osteomalacia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent:

- changes in the levels of certain chemicals in the blood and urine which are usually detected by blood and urine tests (electrolyte imbalance)
- drowsiness, confusion, memory loss, subtle change in personality, impaired reasoning, light headedness
- nausea, vomiting, diarrhoea, constipation, cramping abdominal pain, nausea, thirst
- the intestine (bowel) cannot contract normally and move waste out of the body
- flushing of the skin
- loss of tendon reflexes, muscle weakness.

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 or, 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 GELUSIL-S.

5. How to store GELUSIL-S

Store at or below 25 ºC.

Do not remove blister from the carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label and carton.

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 GELUSIL-S contains

The active substances in GELUSIL-S are aluminium hydroxide dried gel, magnesium hydroxide and simethicone (activated methylpolysiloxane).

Each GELUSIL-S tablet contains 200 mg aluminium hydroxide dried gel, 200 mg magnesium hydroxide and 20 mg simethicone.

(Magnesium content: 3,4 mmol per tablet).

The other ingredients are confectioners' sugar, magnesium stearate, mannitol, natural lemon flavour, spearmint oil redistilled.

What GELUSIL-S looks like and contents of the pack

GELUSIL-S: A white, round, bevel-edged tablet with a lemon-spearmint odour and taste.

GELUSIL-S: PVC Aluminium blister packs of 24 tablets, contained in a printed outer carton.

Holder of Certificate of Registration

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