PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

GELUSIL PLUS, 500 milligram, 267 milligram, 160 milligram, suspension

Sodium alginate, Sodium bicarbonate, Calcium carbonate

Sugar free

Contains sweetener (sodium saccharin dihydrate 7 mg per 10 ml)

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

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

Keep this leaflet. You may need to read it again.

Do not share GELUSIL PLUS 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 o or do not improve after 7 days.

What is in this leaflet

1. What GELUSIL PLUS is and what it is used for
2. What you need to know before you take GELUSIL PLUS
3. How to take GELUSIL PLUS
4. Possible side effects
5. How to store GELUSIL PLUS
6. Contents of the pack and other information

1. What GELUSIL PLUS is and what it is used for

GELUSIL PLUS is used to relieve heartburn (including heartburn during pregnancy), acid ingestion, excessive gas in the stomach associated with acid pushing up into the oesophagus (reflux) and inflammation of the oesophagus. It is also used to treat symptoms of hiatus hernia, where the upper part of your stomach pushes upwards into the opening in your diaphragm through which the oesophagus passes.

2. What you need to know before you take GELUSIL PLUS

Do not take GELUSIL PLUS:

- if you are hypersensitive (allergic) to sodium alginate, sodium bicarbonate, calcium carbonate or to any of the ingredients of GELUSIL PLUS (listed in section 6).

Warnings and precautions

Take special care with GELUSIL PLUS:

- if you are on a highly restricted salt diet
- if you have a kidney disorder
- if you have a liver disorder
- if you have a heart disorder
- if you are retaining fluid (with swelling of the limbs or skin)
- if you have high blood pressure
- if you have aldosteronism (syndrome of high blood pressure and low blood potassium levels)
- if you have eclampsia (a serious complication of pregnancy, characterized by convulsions)
- if you have alkalosis (high levels of base in the body or very low levels of acid in the body)
- if you have too much calcium in the blood
- if your stomach is unable to produce acid

Children

Not recommended for children under 12 years (see section 3).

Other medicines and GELUSIL PLUS

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GELUSIL PLUS suspension with these medicines may cause undesirable interactions. Always tell your healthcare professional if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using certain antibiotic medicines (tetracyclines, fluoroquinolines), medicines used for trouble sleeping (barbiturates), medicines for mood disorders (lithium), thiazide diuretics (used to treat high blood pressure), digoxin (used to treat heart failure), medicines used for osteoporosis (bisphosphonates) and medicine used for pain (salicylates such as aspirin). GELUSIL PLUS may affect the absorption of other oral medicines such as biphosphonates, iron salts, thyroxine, histamine-H_2 antagonists (antacids), ketoconazole, beta blockers, penicillamine, chloroquine, tetracyclines, fluoroquinolones, medicines used for anxiety, fluoride supplements and cortisone medication (for asthma or other inflammatory disorders). These medicines need to be taken 3 hours before or after the use of GELUSIL PLUS.

GELUSIL PLUS with food or drink

GELUSIL PLUS must be taken after meals and before bedtime.

Pregnancy and breastfeeding

GELUSIL PLUS may be used for heartburn during pregnancy.

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

Driving and using machines

It is unlikely for GELUSIL PLUS to cause drowsiness. However, take care until you know how GELUSIL PLUS affects you.

GELUSIL PLUS contains ethyl parahydroxybenzoate and sodium butyl parahydroxybenzoate

GELUSIL PLUS contains ethyl parahydroxybenzoate and sodium butyl parahydroxybenzoate as preservatives which may cause allergic reactions.

GELUSIL PLUS is sugar free.

3. How to take GELUSIL PLUS

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

Always take GELUSIL PLUS suspension exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults and children over 12 years:

Take 10 – 20 ml after meals and before bedtime.

Children under 12 years:

Not recommended.

Elderly:

It is not necessary to change the dose if you are elderly.

If symptoms do not improve or go away in 7 days, please consult a doctor.

If you take more GELUSIL PLUS than you should

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

If you forget to take GELUSIL PLUS

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

4. Possible side effects

GELUSIL PLUS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, 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 allergic reaction to GELUSIL PLUS. You may need urgent medical attention or hospitalisation.

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

- difficulty breathing

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

Tell your doctor if you notice any of the following:

- stomach cramps
- belching
- constipation

- flatulence

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 GELUSIL PLUS.

5. How to store GELUSIL PLUS

- Store at or below 25 ºC.
- Keep the bottle well closed.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use this medicine after the expiry date printed on the label.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GELUSIL PLUS contains

The active substances contained in 10 ml of GELUSIL PLUS are:

Sodium alginate	500 mg
Sodium bicarbonate	267 mg
Calcium carbonate	160 mg

The other ingredients are carboxypolymethylethylene, ethyl parahydroxybenzoate (preservative), hexaflavour aniseed powder, FD&C Red # 40, sodium butyl parahydroxybenzoate (preservative) and sodium saccharin dehydrate.

What GELUSIL PLUS looks like and contents of the pack

A pink smooth suspension with a taste and smell of liquorice.

GELUSIL PLUS is packed into amber soda-lime-silica glass (Type III, USP) bottles with child-proof and tamper evident polypropylene screw caps. The bottle is packed in a carton.

GELUSIL PLUS is available in 200 ml and 500 ml bottles.

Holder of Certificate of Registration

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This leaflet was last revised in

04 May 2021

Registration number

43/11,10/1124