Gelusil-S

PACKAGE INSERT

SCHEDULING STATUS: S0
PROPRIETARY NAME AND DOSAGE FORM:
GELUSIL-S tablets
COMPOSITION:
GELUSIL-S: Each tablet contains 200 mg aluminium hydroxide dried gel, 200 mg magnesium hydroxide and 20 mg simethicone (activated methylpolysiloxane). (Magnesium content: 3,4 mmol per tablet)
Inactive ingredients:
Confectioners' sugar, magnesium stearate, mannitol, natural lemon flavour (ICC-26353), spearmint oil redistilled.
GELUSIL-S tablets contain sugar: 594 mg/tablet and mannitol 120 mg/tablet
PHARMACOLOGICAL CLASSIFICATION:
A 11.4.1 Antacids – Acid neutralisers.
PHARMACOLOGICAL ACTION:
GELUSIL-S is a combination of two antacids, aluminium hydroxide and magnesium hydroxide as well as an anti-foaming agent, simethicone. Simethicone breaks down barriers of foaming mucus, thereby providing effective anti-flatulent action.
INDICATIONS:
GELUSIL-S is indicated for the relief of hyperacidity and flatulence associated with heartburn, gastritis and acid indigestion and as an adjunctive treatment in peptic ulcers.
CONTRAINDICATIONS:
- Known hypersensitivity to aluminium hydroxide, magnesium hydroxide, simethicone or any of the excipients of **GELUSIL-S**
- Patients with impaired renal function or renal failure
- Patients who are severely debilitated
- Contraindicated in children.

WARNINGS AND SPECIAL PRECAUTIONS:
Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of **GELUSIL-S** may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly.
Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets, may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.
In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia or microcytic anaemia.
Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis.
Magnesium hydroxide may cause diarrhoea, an effect that is dose-dependent. Hypermagnesaemia may occur, usually in patients with renal impairment.
Effects on ability to drive and use machines:
GELUSIL-S has no or negligible influence on the ability to operate hazardous machinery, including motor vehicles.
Information on excipients of GELUSIL-S:
GELUSIL-S contains confectioners' sugar. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take **GELUSIL-S**.
GELUSIL-S contains confectioners' sugar which may have an effect on the glycaemic control of patients with *diabetes mellitus*.
INTERACTIONS:
- In general, patients should be advised not to take any oral medication within at least 2 hours of taking **GELUSIL-S**
- **GELUSIL-S** used concurrently with oral tetracyclines, rifampicin, ciprofloxacin, cefdinir, cefpodoxime, methenamine, digoxin, quinidine, oral iron preparations, anticholinergic medicines, barbiturates, quinines, warfarin, vitamins, H_2 receptor antagonists, oral isoniazid, sucralfate, sodium fluoride, ketoconazole, phenytoin, phenothiazines, hydroxychloroquine, chloroquine, chlorpromazine, levothyroxine and rosuvastatin may reduce the absorption of these medicines
- Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine
- Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risk of reduced effectiveness of the resin in binding potassium of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide)
- Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.
DOSAGE AND DIRECTIONS FOR USE:
Adults (including the elderly):
The usual dosage is one or two tablets chewed or allowed to disintegrate 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 **(see CONTRAINDICATIONS)**.

SIDE EFFECTS:

System Organ Class	Frequency	Side Effects
Immune system disorders	*Less frequent*	Hypersensitivity reactions, pruritus, urticaria, angioedema, anaphylactic reactions
Metabolism and nutrition disorders	*Less frequent*	Hypermagnesaemia* (due to prolonged use, large doses and/or renal disease). Symptoms may include flushing of the skin, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac dysrhythmias, coma and cardiac arrest Hyperaluminemia, hyperphosphatemia, low-phosphate diets may lead to phosphate depletion with increased bone resorption and hypercalciuria with the risk of osteomalacia**
Psychiatric disorders	*Less frequent*	Encephalopathy and dementia in patients with chronic renal failure receiving high doses,** confusion
Nervous system disorders*	*Less frequent*	Drowsiness, neuromuscular blockade, coma
Cardiac disorders*	*Less frequent*	Cardiac dysrhythmias, cardiac arrest
Vascular disorders*	*Less frequent*	Peripheral vasodilation, hypotension due to peripheral vasodilation
Respiratory, thoracic and mediastinal disorders*	*Less frequent*	Respiratory depression
Gastrointestinal disorders	*Less frequent*	Nausea**, vomiting**, diarrhoea**, constipation**, intestinal obstruction due to large doses**, ileus, thirst
Skin and subcutaneous tissue disorders*	*Less frequent*	Flushing of the skin
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Loss of tendon reflexes due to neuromuscular blockade*, muscle weakness*, osteomalacia due to high doses in patients with low-phosphate diets and patients with chronic renal failure**
Renal and urinary disorders	*Less frequent*	Renal dysfunction, renal failure.

* Side effects specific to magnesium
** Side effects specific to aluminium hydroxide

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Serious symptoms are unlikely following overdosage.
Reported symptoms of acute overdose with **GELUSIL-S** include diarrhoea, abdominal pain, vomiting.
Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk **(see WARNINGS AND SPECIAL PRECAUTIONS and SIDE EFFECTS)**.
Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV calcium gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.
IDENTIFICATION:
GELUSIL-S: A white, round, bevel-edged tablet with a lemon-spearmint odour and taste.
PRESENTATION:
GELUSIL-S: PVC Aluminium blister packs of 24 tablets, contained in a printed outer carton.
STORAGE INSTRUCTIONS:
Store at or below 25 ºC.
Do not remove blister from the carton until required for use.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBERS:
E/11.4.1/633 **NAM** NS0 04/11.4.1/1519 **BOT** S2 BOT9700045
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
iNova Pharmaceuticals (Pty) Ltd, Co. Reg. No. 1952/001640/07
15E Riley Road, Bedfordview, 2007, Tel: +27 (0) 11 087 0000
www.inovapharma.co.za
DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of registration: 24 March 1993
Date of publication: 20 March 2017

30 mm
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250 mm

Gelusil-S

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S0
PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
GELUSIL-S tablets
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 pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. 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.
GELUSIL-S tablets contain sugar: 594 mg/tablet and mannitol 120 mg/tablet
2. WHAT GELUSIL-S 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.

3. 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 (see WHAT GELUSIL-S CONTAINS)**
- 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 HOW TO TAKE GELUSIL-S)**.
Take special care with GELUSIL-S:
- if you are on a low phosphorous diet as the use of **GELUSIL-S** may lead to the softening of your bones (osteomalcia)
- 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.
Taking GELUSIL-S with food and drink:
GELUSIL-S must preferably be taken between meals.
Pregnancy and breastfeeding:
Safety:
Safe use of **GELUSIL-S** during pregnancy and breastfeeding has not been established.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **GELUSIL-S**.
Driving and using machinery:
GELUSIL-S should not impair your ability to drive or operate heavy machines.
Important information about some of the ingredients of GELUSIL-S:
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**.
GELUSIL-S contains confectioners' sugar which may have an effect on the control of your blood sugar if you have *diabetes mellitus*.
Taking other medicines with GELUSIL-S:
Always tell your healthcare professional if you are taking other medicine. (This includes 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)
- 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 that alter the heart rate (such as digoxin or quinidine)
- 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 containing rosuvastatin used to prevent heart diseases and lower cholesterol made by the liver.

Medicines which may result in increased aluminium levels in the blood include:
- Antacids and ulcer medication, especially in people who suffer from kidney problems.

4. HOW TO TAKE GELUSIL-S:
Do not share medicines prescribed for you with any other person. Always take **GELUSIL-S** exactly as instructed in this leaflet. You should check with your doctor or pharmacist if you are unsure.
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 control 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.
5. POSSIBLE SIDE EFFECTS:
GELUSIL-S may 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 doctor, pharmacist or other healthcare professional 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 allergic 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
- 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.
6. STORING AND DISPOSING OF 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).
7. PRESENTATION OF GELUSIL-S:
GELUSIL-S:
PVC Aluminium blister packs of 24 tablets, contained in a printed outer carton.
8. IDENTIFICATION OF GELUSIL-S:
GELUSIL-S:
A white, round, bevel-edged tablet with a lemon-spearmint odour and taste.
9. REGISTRATION NUMBER
E/11.4.1/633
NAM NS0 04/11.4.1/1519 **BOT** S2 BOT9700045
10. NAME AND ADDRESS OF REGISTRATION HOLDER
iNova Pharmaceuticals (Pty) Ltd, Co. Reg. No. 1952/001640/07
15E Riley Road, Bedfordview, 2007, Tel: +27 (0) 11 087 0000
11. DATE OF PUBLICATION:
Date of registration: 24 March 1993
Date of publication: 20 March 2017
026723 2020A

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Gelusil-S

VOUBILJET

SKEDULERINGSTATUS: S0
EIENDOMSNAAM EN DOSEERVORM:
GELUSIL-S tablette
SAMESTELLING:
GELUSIL-S: Elke tablet bevat 200 mg gedroogde aluminiumhidroksied jel, 200 mg magnesiumhidroksied en 20 mg simetikoon (geaktiveerde metielpolisiloksaan). (Magnesiuminhoud: 3,4 mmol per tablet)
Onaktiewe bestanddele:
Hergedistilleerde groenment olie, magnesiumstearaat, mannitol, natuurlike suurlemoengeur (ICC-26353), versiersuiker.
GELUSIL-S tablette bevat suiker: 594 mg/tablet en mannitol 120 mg/tablet
FARMAKOLOGIESE KLASSIFIKASIE:
A 11.4.1 Teensuurmiddels – Suurneutraliseerders.
FARMAKOLOGIESE WERKING:
GELUSIL-S is 'n kombinasie van twee teensuurmiddels, aluminiumhidroksied en magnesiumhidroksied, sowel as 'n skuimwerende middel, simetikoon. Simetikoon breek skuimende mukus-skanse af, en werk sodoende winderigheid doeltreffend teë.
INDIKASIES:
GELUSIL-S word teenaangedui vir die verligting van hiperasiditeit en flatulensie, wat met sooibrand, gastritis en suur-indigestie verband hou. Dit word ook aangedui as bykomende behandeling vir peptiese ulkusse.
KONTRA-INDIKASIES:
- Bekende hipersensitiwiteit vir aluminiumhidroksied, magnesiumhidroksied, simetikoon, of enige van die eksipiënte van **GELUSIL-S**
- Pasiënte met belemmerde renale funksie of nierversaking
- Pasiënte wie erg afgetakel is
- Teenaangedui by kinders.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Aluminiumhidroksied mag konstipasie veroorsaak en magnesiumsout oordosering, mag hipomotiliteit van die ingewande tot gevolg hê; groot dosisse **GELUSIL-S** mag intestinale obstruksie en ileus veroorsaak, of vererger by pasiënte met 'n hoër risiko, soos dié met renale belemmering of by bejaardes.
Aluminiumhidroksied word nie goed vanuit die gastro-intestinale kanaal geabsorbeer nie en sistemiese uitwerking is dus skaars by pasiënte met normale renale funksie. Oormatige dosisse of langtermyn gebruik, of selfs normale doserings by pasiënte lae-fosfor diete, mag egter lei tot fosfaat uitputting (weens aluminium-fosfaat binding), gepaardgaande met 'n toename in beenresorpsie en hiperkalsiurie, met 'n risiko vir osteomalasie. Mediese advies word aanbeveel in die geval van langtermyn gebruik, of by pasiënte met 'n risiko vir fosfaat uitputting.
By pasiënte met renale belemmering, neem plasmavlakke van beide aluminium en magnesium toe. By hierdie pasiënte, mag 'n langtermyn blootstelling aan hoë dosisse aluminium- en magnesiumsoute lei tot demensie of mikrolitiese anemie. Aluminiumhidroksied mag onveilig wees vir pasiënte met porfirie, wat hemodialise ondergaan.
Magnesiumhidroksied mag diarree veroorsaak, 'n uitwerking wat dosisafhanklik is. Hipermagnesemie mag voorkom, gewoonlik by pasiënte met renale belemmering.
Effekte op die vermoë om te bestuur en masjinerie te hanteer:
GELUSIL-S het geen of 'n onbeduidende invloed op die vermoë om gevaarlike masjinerie, insluitend motorvoertuie te hanteer.
Inligting omtrent sommige van die eksipiënte van GELUSIL-S:
GELUSIL-S bevat versiersuiker. Pasiënte met skaars oorerflike toestande soos fruktose onverdraagsaamheid, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid, moet nie **GELUSIL-S** neem nie.
GELUSIL-S bevat versiersuiker, wat 'n uitwerking mag hê op die glisemiese beheer van pasiënte met *diabetes mellitus.*
INTERAKSIES:
- Oor die algemeen moet pasiënte aangeraai word om nie enige orale medikasie te neem binne ten minste twee ure vandat **GELUSIL-S** geneem is nie
- **GELUSIL-S** wat gelyktydig saam met orale tetrasikliene, rifampisien, siprofloksasien, sefdinir, sefpodoksiem, metenamien, digoksien, kinidien, orale ysterpreparate, anticholinergiese medisynes, barbiturate, kiniene, warfarien, vitamiene, H_2 reseptor antagoniste, orale isoniasied, sukralfaat, natriumfluoried, ketokonasool, fenitoïen, fenotiasiene, hidrochlorokien, chlorokien, chloorproma sien, levotiroksien en rosuvastatien geneem word, mag die absorpsie van hierdie medisyne verlaag
- Levotiroksien mag ook aan simetikoon bind, wat die die absorpsie van levotiroksien mag vertraag of verlaag
- Omsigtigheid word aanbeveel met die gelyktydige gebruik saam met polistireensulfonaat, weens die potensiële risiko vir die afname in doeltreffendheid van die harsbinding van kalium in metaboliese alkalose by pasiënte met nierversaking (aangemeld met aluminiumhidroksied en magnesiumhidroksied), en intestinale obstruksie (aangemeld met aluminiumhidroksied)
- Aluminiumhidroksied en sitrate mag lei tot 'n toename in aluminiumvlakke, veral by pasiënte met renale belemmering.

SWANGERSKAP EN LAKTASIE:
Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes (insluitend bejaardes):
Die gewone dosis is een of twee tablette gekou, of toegelaat om te disintegreer in die mond, 4 tot 8 maal per dag, verkieslik tussen maaltye, of soos aanbeveel deur 'n dokter of apteker.
Moet nie meer as 16 tablette in 'n 24 uur tydperk neem nie.
Moet nie die maksimum dosis **GELUSIL-S** vir meer as 2 weke gebruik, behalwe onder die aanbeveling en toesig van 'n dokter nie.
Kinders:
Nie aanbeveel vir gebruik by kinders nie **(kyk KONTRA-INDIKASIES**).

NEWE-EFFEKTE:

Orgaanstelsel Klas	Frekwensie	Newe-effekte
Immuunstelsel versteurings	*Minder dikwels*	Hipersensitiwiteitsreaksies, pruritus, urtikarie, angio-edeem, anafilaktiese reaksies
Metabolisme en voedingsteurings	*Minder dikwels*	Hipermagnesemie* (weens verlengde gebruik, groot dosisse en/of renale siekte). Simptome mag velblosing, dors, hipotensie weens perifere vasodilasie, lomerigheid, verwarring, verlies van tendonreflekse weens neuromuskulêre blokkade, spierswakheid, respiratoriese onderdrukking, kardiale disritmieë, koma en kardiale arres. Hiperaluminemie, hiperfosaftemie, lae-fosfor diete mag lei tot fosfaat uitputting met 'n toename in beenresorpsie en hiperkalsiurie, met die risiko vir osteomalasie**
Psigiatriese versteurings	*Minder dikwels*	Ensefalopatie en demensie by pasiënte met chroniese nierversaking wat hoë dosisse ontvang,** verwarring
Senuweestelsel versteurings*	*Minder dikwels*	Lomerigheid, neuromuskulêre blokkade, koma
Kardiale versteurings*	*Minder dikwels*	Kardiale disritmieë, kardiale arres
Vaskulêre versteurings*	*Minder dikwels*	Perifere vasodilasie, hipotensie weens perifere vasodilasie
Respiratoriese, torakaal en mediastinale versteurings*	*Minder dikwels*	Respiratoriese onderdrukking
Gastro-intestinale versteurings	*Minder dikwels*	Narrheid**, braking**, diarree**, konstipasie**, intestinale obstruksie weens hoë dosisse**, ileus, dors
Vel- en onderhuidse weefselversteurings*	*Minder dikwels*	Velblosing
Muskuloskeletale, bindweefsel en beenversteurings	*Minder dikwels*	Verlies van tendonreflekse weens neuromuskulêre blokkade*, spierswakheid*, osteomalasie, weens hoë dosisse by pasiënte op lae-fosfor diete en pasiënte met chroniese nierversaking**
Renale en urinêre versteurings	*Minder dikwels*	Renale wanfunksie, nierversaking

* Newe-effekte spesifiek vir magnesium
** Newe-effekte spesifiek vir aluminiumhidroksied
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Ernstige simptome is onwaarskynlik na 'n oordosering.
Simptome wat aangemeld is na 'n akute oordosis met **GELUSIL-S** sluit diarree, abdominale pyn, braking in.
Groot dosisse van hierdie produk mag intestinale obstruksie en ileus veroorsaak of vererger by risiko pasiënte **(kyk WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS en NEWE-EFFEKTE).**
Aluminium en magnesium word deur die urinêre roete uitgeskei; behandeling van akute oordosering bestaan uit die toediening van IV kalsiumglukonaat, rehidrasie en geforseerde diurese. In die geval van renale funksie ontoereikendheid, word hemodialise of peritoneale dialise benodig.
IDENTIFIKASIE:
GELUSIL-S:
'n Wit, ronde skuinskantige tablet met 'n suurlemoen-groenment geur en smaak.
AANBIEDING:
GELUSIL-S:
PVC Aluminium stulpstrook verpakkings van 24 tablette, binne-in 'n gedrukte buitenste kartonhouer.
BERGINGSAANWYSINGS:
Bewaar teen of benede 25 ºC.
Moet nie die stulpstrook vanuit die kartonhouer verwyder totdat dit benodig word vir gebruik nie.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMERS:
E/11.4.1/633 **NAM** NS0 04/11.4.1/1519 **BOT** S2 BOT9700045
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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PUBLIKASIEDATUM:
Registrasiedatum: 24 Maart 1993
Publikasiedatum: 20 Maart 2017

Gelusil-S

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S0
EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:
GELUSIL-S tablette
Lees hierdie hele inligtingsblad deeglik deur want dit bevat belangrike inligting vir u.
GELUSIL-S is beskikbaar sonder 'n dokter se voorskrif vir u, om 'n minder ernstige siekte te behandel. U moet nietemin **GELUSIL-S** versigtig gebruik, om die beste resultate daarvan te verkry.
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees
- Moet nie **GELUSIL-S** met enige ander persoon deel nie
- Vra u apteker indien u meer inligting of advies benodig
- U moet 'n dokter besoek indien u simptome versleg of nie verbeter nie.

1. WAT GELUSIL-S BEVAT:
Die aktiewe bestanddele in **GELUSIL-S** is gedroogde aluminiumhidroksied jel, magnesiumhidroksied en simetikoon (geaktiveerde metielpolisiloksaan).
Elke **GELUSIL-S** tablet bevat 200 mg gedroogde aluminiumhidroksied jel, 200 mg magnesiumhidroksied en 20 mg simetikoon.
(Magnesiuminhoud: 3,4 mmol per tablet).
Die ander bestanddele is bakkersuiker (versiersuiker), hergedistilleerde groenment olie, magnesiumstearaat, mannitol, natuurlike suurlemoengeur.
GELUSIL-S tablette bevat suiker.
2. WAARVOOR GELUSIL-S GEBRUIK WORD:
GELUSIL-S behoort aan 'n groep medisynes wat teensuurmiddels genoem word.
GELUSIL-S word gebruik:
- vir die verligting van dispepsie (indigestie)
- vir sooibrand, opgeblaasdheid of flatulensie (oormatige winderigheid)
- in die beheer van maagsere, as aanvullende behandeling.

3. VOORDAT U GELUSIL-S NEEM:
Moet nie **GELUSIL-S** neem:
- indien u hipersensitief (allergies) is vir aluminiumhidroksied, magnesium, simetikoon of enige van die ander bestanddele van **GELUSIL-S** nie **(kyk WAT GELUSIL-S BEVAT)**
- indien u nierversaking het nie (swelling van die enkels en voete), en indien u belemmerdie nierfunksie het nie (u laat geen of baie min urine per dag)
- indien u afgetakel is nie (voel baie swak en het geen energie nie).

GELUSIL-S moet nie aan kinders gegee word nie **(kyk HOE OM GELUSIL-S TE NEEM)**.
Neem spesiale sorg met GELUSIL-S:
- indien u op 'n lae fosfordieet is, aangesien die gebruik van **GELUSIL-S** mag lei tot die versagting van u bene (osteomalasie)
- indien u porfirie het ('n skaars oorerflike siekte waar daar abnormale metabolisme van die bloedpigment, hemoglobien voorkom) en hemodialise ondergaan
- hoë dosisse **GELUSIL-S** mag intetsinale obstruksie veroorsaak of vererger, met simptome soos krampende abdominale pyn, naarheid, konstipasie
- indien u nierprobleme het, aangesien langtermyn blootstelling mag lei tot die verlies van u vermoë om te dink en redeneer, of 'n bloedversteuring wat mikrositiese anemie genoem word
- hoë dosisse **GELUSIL-S** mag diarree en hipermagnesemie ('n toestand waar daar 'n hoë vlak magnesium in u bloed is), veroorsaak by mense met nierprobleme
- indien u 'n bejaarde pasiënt is.

U dokter mag toetse aanvra om u toestand te moniteer vóór of tydens behandeling.
Die neem van GELUSIL-S saam met kos en drinkgoed:
GELUSIL-S moet verkieslik tussen maaltye geneem word.
Swangerskap en borsvoeding:
Veiligheid:
Veilige gebruik van **GELUSIL-S** tydens swangerskap en borsvoeding is nie vasgestel nie.
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies voordat u **GELUSIL-S** neem.
Bestuur en die hantering van masjinerie:
GELUSIL-S behoort nie 'n vermoë om te bestuur, of swaar masjinerie te hanteer, belemmer nie.
Belangrike inligting omtrent sommige van die bestanddele van GELUSIL-S:
GELUSIL-S bevat versiersuiker. Indien u deur u dokter vertel is dat u 'n onverdraagsaamheid het teenoor sekere suikers, kontak u dokter voordat u **GELUSIL-S** neem.
GELUSIL-S bevat versiersuiker, wat 'n invloed op die beheer van u bloedsuiker mag hê indien u *diabetes mellitus* het.
Die neem van ander medisynes saam met GELUSIL-S:
Vertel altyd u professionele gesondheidsorgwerker indien u ander medisyne neem. (Dit sluit komplementêre of tradisionele medisynes in).
Moet nie enige ander orale medikasie neem binne ten minste 2 uur vandat **GELUSIL-S** geneem is nie.
GELUSIL-S mag die absorpsie van die volgende medisynes verlaag:
- Sekere antibiotika (soos orale tetrasikliene, rifampisien, siprofloksasien, sefdinir, sefpodoksiem, metenamien)
- Sekere swamwerende medisynes (soos ketokonasool)
- Medisynes wat kiniene genoem word, vir die voorkoming van malaria en behandeling van rumatoïede artritis (soos hidroksichlorokien chlorokien)
- Medisynes wat die harttempo verander (soos digoksien of kinidien)
- Sekere medisynes wat gebruik word om geestestoestande te behandel (soos chloorpromasien)
- Sekere medisynes wat gebruik word om onderaktiewe tiroïed te behandel (soos levotiroksien), aangesien die uitwerking van hierdie medisyne verlaag mag word deur **GELUSIL-S**
- Medisynes wat gebruik word om hoë kaliumvlakke in u bloed te behandel (soos polistireensulfonaat), aangesien die uitwerking van hierdie medisynes verlaag mag word deur **GELUSIL-S**
- Vitamiene, aangesien die uitwerking van vitamiene verlaag mag word
- Medisynes wat gebruik word om tuberkulose te behandel (isoniasied, rifampisien)
- Ander medisyne wat gebruik word om maagsuur te verminder en H_2 antagoniste genoem word
- Fenitoïen, wat gebruik word om epilepsie te behandel
- Orale ysterpreparate wat gebruik word om ystertekort te voorkom en te behandel
- Medisynes wat gebruik word om onwillekeurige spierbewegings te blokkeer
- Sedeermiddels en slaap-induserende medisynes gemaak van barbituursuur
- Medisynes wat warfarien bevat en gebruik word om die vorming van bloedklonte te verminder
- Medisynes soos sukralfaat, wat gebruik word om aktiewe duodenale ulkusse te behandel
- Medisynes wat die chemikalie natriumfluoried bevat en wat gebruik word om tandkaviteite te verhoed
- Medisynes (soos fenotiasien), wat gebruik word om skisofrenie te behandel
- Medisynes wat rosuvastatien bevat om hartsiekte te verhoed en cholesterol, wat deur die lewer gevorm word, te verlaag

Medisynes wat 'n toename in aluminiumvlakke in die bloed mag veroorsaak sluit in:
- Teensuurmiddels en ulkusmedikasie, veral by mense wie aan nierprobleme ly.

4. HOE OM GELUSIL-S TE NEEM:
Moet nie medisynes wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **GELUSIL-S** presies soos in hierdie inligtingsblad voorgeskryf is. U moet met u dokter of apteker nagaan indien u onseker is.
Volwassenes (insluitend bejaardes):
Die gewone dosis is een of twee tablette gekou, of toegelaat om op te los in die mond 4 tot 8 maal per dag, verkieslik tussen maaltye, of soos aanbeveel deur 'n dokter of apteker.
Moet nie meer as 16 tablette in 'n 24 uur tydperk neem nie.
Moet nie die maksimum dosis **GELUSIL-S** vir meer as 2 weke neem, behalwe onder die advies en toesig van 'n dokter nie.
Kinders:
Nie aanbeveel vir gebruik by kinders nie.
Indien u onder die indruk is dat die uitwerking van **GELUSIL-S** té sterk of té swak is, vertel u dokter of apteker.
Indien u meer GELUSIL-S neem as wat u behoort:
In die geval van 'n oordosis, kontak u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Simptome van oordosering mag diarree, abdominale pyn en braking, insluit.
Indien u vergeet om 'n dosis GELUSIL-S te neem:
Indien u vergeet om 'n dosis **GELUSIL-S** te neem, neem die oorgeslane dosis so gou as wat u onthou. Indien dit amper tyd is vir u volgende dosis, slaan die dosis wat gemis is oor, en hou aan om die tablet of tablette, op die gewone tyd te neem. Moet nie 'n dubbel of groter dosis neem om op te maak vir die vergete individuele dosisse nie.
5. MOONTLIKE NEWE-EFFEKTE:
GELUSIL-S mag newe-effekte hê. Nie alle newe-effekte wat vir **GELUSIL-S** aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar terwyl u **GELUSIL-S** neem, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, staak die gebruik van **GELUSIL-S** en vertel u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, lippe, mond of keel wat sluk of asemhaling mag bemoeilik
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie vir **GELUSIL-S** gehad het. U mag dringende mediese aandag of hospitalisasie benodig.
Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- hipermagnesemie: 'n toestand waar daar 'n ongewone hoë magnesiumvlak in u liggaam is (u mag velblosing, dors, duiselige gevoel of lighoofdigheid, lomerigheid, verwarring, spierswakheid of –styfheid, asemhalingsprobleme, vinnige of onreëlmatige hartklop, ervaar)
- borsongemak of pyn, kortasemheid, aangesien hierdie simptome mag wees van 'n hartaanval
- onreëlmatige hartklop (kardiale disritmieë), koma
- moeilike asemhaling
- moeite om te fokus, geheueverlies, moeite met probleemoplossingsvaardighede (moontlike tekens van 'n breinsiekte)
- lae bloeddruk (voel duiselig)
- abnormale nierfunksie, soos minder urine as gewoonlik, uitputting en swakheid
- beenpyn, bene wat maklik breek (osteomalasie).

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.
Vertel u dokter indien u enige van die volgende opmerk:
Minder dikwels:
- veranderinge in die chemikalie-vlakke in die bloed en urine, wat gewoonlik opgetel word deur bloed- en urinetoetse (elektrolietwanbalans)
- lomerigheid, verwarring, geheueverlies, subtiele veranderinge in persoonlikheid, belemmerde redenasie, lighoofdigheid
- naarheid, braking, diarree, konstipasie, krampende abdominale pyn, naarheid, dors
- velblosing
- verlies van tendonreflekse, spierswakheid.

Indien u enige newe-effekte wat nie in hierdie inligtingsblad genoem word nie, opmerk, lig asseblief u dokter of apteker in.
6. BEWARING EN WEGDOENING VAN GELUSIL-S:
Bewaar teen of benede 25 ºC.
Moet nie die stulpstrook vanuit die kartonhouer verwyder totdat dit benodig word vir gebruik nie.
Bewaar alle medisyne buite die bereik van kinders.
Moet nie gebruik na die vervaldatum wat op die etiket en kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
7. AANBIEDING VAN GELUSIL-S:
GELUSIL-S:
PVC Aluminium stulpstroke van 24 tablette, in 'n gedrukte buitenste kartonhouer.
8. IDENTIFIKASIE VAN GELUSIL-S:
GELUSIL-S:
'n Wit, ronde, skuinskantige tablet met 'n suurlemoen-groenment geur en smaak.
9. REGISTRASIENOMMER
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NAM NS0 04/11.4.1/1519 **BOT** S2 BOT9700045
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11. PUBLIKASIEDATUM:
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BRITEPAK