SCHEDULING STATUS **S0**

1. NAME OF THE MEDICINE

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:	Sodium alginate	500 mg
	Sodium bicarbonate	267 mg
	Calcium carbonate	160 mg

Excipient with known effect:

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

Preservatives:	Ethyl parahydroxybenzoate	0,2 %
	Sodium butyl parahydroxybenzoate	0,02 %

GELUSIL PLUS is sugar free.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GELUSIL PLUS suspension is indicated for:

Gastric reflux, reflux oesophagitis, heartburn (including heartburn during pregnancy), symptoms of hiatus hernia, flatulence associated with gastric reflux and all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

4.2 Posology and method of administration

Posology

Adults and children over 12 years: Take 10 – 20 ml after meals and before bedtime.

Elderly: No modifications in dosage necessary for this age group.

If symptoms of gastro-oesophageal reflux do not improve within 7 days, the clinical situation should be reviewed by a medical practitioner.

Paediatric population

Children under 12 years: Treatment is not recommended.

Method of administration

For oral administration

4.3 Contraindications

Hypersensitivity to sodium alginate, sodium bicarbonate, and calcium carbonate or to any of the ingredients of GELUSIL PLUS as listed in section 6.1.

4.4 Special warnings and precautions for use

GELUSIL PLUS suspension contains approximately 133,80 mg and/or 5,82 mmol of sodium per 10 millilitres of suspension. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality. As congestive cardiac failure may result from excessive sodium absorption, GELUSIL PLUS suspension should be administered with caution to patients on a highly restricted salt diet, and with renal impairment.

Sodium bicarbonate, such as in GELUSIL PLUS, should be given extremely cautiously to patients with heart failure, oedema, renal impairment, liver cirrhosis, hypertension, eclampsia or aldosteronism. Prolonged use of GELUSIL PLUS may lead to gastric hypersecretion and acid rebound.

Bicarbonate compounds, such as in GELUSIL PLUS, should not be given to patients with metabolic or respiratory alkalosis, or hypochlorhydria. During treatment of acidosis, frequent monitoring of serum-electrolyte concentrations and acid-base status is essential.

Excessive use of bicarbonate compounds may lead to hyperkalaemia and metabolic alkalosis, especially in patients with impaired renal function.

Calcium carbonate can cause hypercalcaemia/alkalosis, nephrocalcinosis or recurrent calcium containing calculi, particularly in patients with renal impairment or after high doses. There have been reports of the milk-alkali syndrome associated with calcium carbonate. There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

GELUSIL PLUS contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

For children below 12 years, please see section 4.2.

4.5 Interactions with other medicines and other forms of interactions

Sodium bicarbonate

Alkalinisation of the urine by GELUSIL PLUS may lead to increased renal clearance of acidic medicines such as salicylates, tetracyclines and barbiturates.

Conversely, GELUSIL PLUS may prolong the half-life of basic medicines and may result in toxicity.

Sodium bicarbonate contained in GELUSIL PLUS enhances lithium excretion.

Calcium carbonate

Hypercalcaemia has occurred when calcium salts are given with thiazide diuretics. Thiazide diuretics decrease its urinary excretion.

Calcium, such as in GELUSIL PLUS, enhances the effects of digoxin on the heart and may precipitate digoxin intoxication.

Calcium salts, such as contained in GELUSIL PLUS, reduce the absorption of a number of other medicines such as bisphosphonates, thyroxine, histamine-H_2 antagonists, iron salts, ketoconazole, neuroleptics, beta blockers, penicillamine, glucocorticoids, chloroquine, fluoride, some fluoroquinolones and tetracyclines. Doses should be separated by at least three hours.

4.6 Fertility, pregnancy and lactation

Pregnancy

GELUSIL PLUS may be used for heartburn during pregnancy (see section 4.1).

Calcium crosses the placenta.

Breastfeeding

Calcium in GELUSIL PLUS is distributed into breast milk.

4.7 Effects on ability to drive and use machines

None reported

4.8 Undesirable effects

Immune system disorders	Less frequent	Hypersensitivity, urticaria, bronchospasm, anaphylactic or anaphylactoid reactions.

Metabolism and nutrition disorders Calcium carbonate	Unknown frequency	Alkalosis, milk-alkali syndrome, hypercalcaemia.
Respiratory, thoracic and mediastinal disorders	Unknown frequency	Respiratory effects such as bronchospasm
Gastrointestinal disorders		
Sodium bicarbonate	Unknown frequency	Stomach cramps, belching and flatulence.
Calcium carbonate	Unknown frequency	Constipation, flatulence.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See Section 4.8.

Large doses of GELUSIL PLUS suspension may produce a feeling of abdominal distension.

Treatment of an overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.11.10 Medicines acting on gastro-intestinal tract.

Antacids Special combinations.

Pharmacotherapeutic classification: A02BX13. Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

Sodium alginate reacts with the gastric acid to form a viscous gel (often termed a Raft) that floats on top of the gastric contents. This raft acts as a mechanical barrier to reduce reflux.

Sodium bicarbonate neutralises gastric acid with the production of carbon dioxide.

5.2 Pharmacokinetic properties

Sodium Bicarbonate

Bicarbonate, not involved in this reaction, is absorbed. In the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine. The urine is therefore rendered alkaline and there is an accompanying diuresis.

Calcium Carbonate

Calcium carbonate is converted to calcium chloride by gastric acid. A part of the calcium is absorbed from the intestines and the unabsorbed part is excreted in the faeces, together with the calcium which is secreted in the bile and pancreatic juice.

Sodium Bicarbonate

Bicarbonate, not involved in this reaction, is absorbed. In the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine. The urine is therefore rendered alkaline and there is an accompanying diuresis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl parahydroxybenzoate 0,2 % (as preservative)

Sodium butyl parahydroxybenzoate 0,02 % (as preservative)

Carboxypolymethylethylene

Hexaflavour aniseed powder

FD&C Red # 40

Sodium saccharin dihydrate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

6.4 Special precautions for storage

Store at or below 25 ºC. Keep the bottle well closed.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

No special requirement.

7. HOLDER OF CERTIFICATE OF REGISTRATION

iNOVA PHARMACEUTICALS (PTY) LTD

15e Riley Road

Bedfordview

South Africa

2007

8. REGISTRATION NUMBER

43/11.10/1124

9. DATE OF FIRST AUTISATATION/RENEWAL OF AUTHORISATION

06 August 2015

10. DATE OF REVISION OF THE TEXT

04 May 2021