

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name:	Gastomac
Generic Name:	Malgadrate 540 mg, Simethicone 100mg

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1.0 Name of the Medicinal Product:

Gastomac Antacid Suspension

2.0 Qualitative and quantitative composition:

Each 5ml contains:
Malgadrate 540mg
Simethicone 100mg

3.0 Pharmaceutical form:

Suspension

4.0 Clinical particulars:

4.1 Therapeutic indication:

Gastomac is used to treat ulcerative and gastric pain, heart burn, oesophageal reflux hyperacidity and indigestion. Magaldrate is an antacid. It neutralizes and reduces stomach acid relieving heartburn and indigestion. It is used to treat an upset stomach, ulcers, hiatal hernia and other digestive disorders. Simethicone is an antifoaming medicine which disintegrates gas bubbles and allows easy passage of gas.

4.2 Posology and method of administration:

Unless or otherwise recommended by your physician, 5ml to 10ml 3 to 4 times daily after meal. Children under 12 years should follow the direction of their physician.

4.3 Contraindications:

Do not use if you are presently taking a prescription antibiotic drug containing any form of tetracycline, iron salts, multivitamin supplement containing citrate, chlorpromazine, levodopa, isoniazid, digoxin, H₂-antagonists, indomethacin and dicumarol.

4.4 Special warnings and precautions for use

There are no common or important side effect reported. This medication is generally well tolerated. Loss of appetite, diarrhoea or constipation may occur. Notify your doctor if you develop vomiting of coffee ground-like material, dark urine, tar-like stools. If you notice other effects not listed above, contact your doctor or pharmacist. If you are on low-magnesium diet, talk to your doctor. If you are pregnant or planning to be pregnant, breast feeding you need to talk about the risks and benefits of using simethicone.

Precautions: Tell your doctor if you have stomach disorders.

4.5 Interaction with other medicinal products and other forms of interaction:

Medications known to interact with simethicone are levothyroxine, liothyronine liotrix and thyroid desiccated.

4.6 Fertility, pregnancy and lactation:

Magaldrate-simethicone has not been formally assigned to a pregnancy category by the FDA. Animal studies have not been reported. There are no controlled data in human pregnancy. Magaldrate-simethicone is only recommended for use during pregnancy when

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benefit outweighs risk. Hence, there are limited amount of data with respect to the use of in pregnant women.

4.7 Effects on ability to drive and use machines:

None

4.8 Undesirable effects:

Bad taste in the mouth, chalky taste, constipation, loose stool, upset stomach or throwing up

4.9 Overdose:

If you think there has been an overdose, get medical care right away.

5.0 Pharmacological properties:

5.1 Pharmacodynamic properties:

Simethicone is not systemically absorbed and so these data are not readily available. However, Simethicone is indicated for the treatment of bloating, pressure, and cramps caused by gas. Simethicone is also used as part of bowel preparation for colonoscopies.

Simethicone decreases the surface tension of gas bubbles in the gastrointestinal tract, facilitating their expulsion. It has a short duration of action as it is generally given as needed, and a wide therapeutic index as it is not systemically absorbed.

5.2 Pharmacokinetic properties:

Aluminium oxide: absorbed Al ions are eliminated in the urine (0.1-0.5 mg of Al in aluminium-containing antacid is absorbed from standard daily doses of antacid) while insoluble or poorly absorbed Al salts in the intestines are excreted through the feces. Magnesium oxide: absorbed Mg ions (up to 30%) are eliminated in the urine, unabsorbed is excreted in the feces.

Simethicone is eliminated in the faeces

6.0 Pharmaceutical particulars:

6.1 List of excipients

Refined Sugar
Sorbitol Solution 70%
Glycerine
Avicel RC581
Xanthan Gum
Methylparaben
Propylparaben
Potassium Sorbate
Citric Acid Monohydrate
Tween 80
Sodium Benzoate
Sodium CMC
Peppermint Oil
Orange Flavour (Liquid)
Aerosil 200
DM Water

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6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30, protected from light. Keep the bottle tightly closed.

6.5 Nature and contents of container

The antacid are filled, capped and packed in 180ml amber pet bottles/ pack
Each pack contains a dosage cup.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0 Manufacturer:

NALIS PHARMACEUTICALS LIMITED.

Plot R67/R68, Nekede-Naze Ind. Cluster, Nekede, Owerri, Imo State

Applicant:

STERLING BIOPHARMA LTD.

6, Femi Asiwaju Close, Ojodu Estate, Ojodu, Lagos.