SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Mucogel Suspension

2. Qualitative and quantitative composition
Each 5ml contains:

Magaldrate USP 400mg

Simethicone USP 20mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Oral 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 alow-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

4.7 Effects on ability to drive and use machines

Mucogel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal side-effects are uncommon. This formulation minimises the problems of diarrhoea and constipation.

Metabolism and nutrition disorders

Very rare (<1(10,000)

Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.

Gastrointestinal disorders

Not known (cannot be estimated from the available data)

Abdominal pain.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Serious symptoms are unlikely to follow overdosage.

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.

After opening: 28 days.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

High density polyethylene (HDPE) bottle with a HDPE closure fitted with a tamper evident ring.

Pack sizes: 100 ml, 120 ml, 125 ml, 200 ml, 240 ml, 250 ml, 300 ml and 500 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
Europa Healthcare Limted

8. Marketing authorisation number(s)
H2024/CTD8459/15264

9. Date of first authorisation/renewal of the authorisation
4TH September 2026

10. Date of revision of the text
4TH September 2026