SUMMARY OF PRODUCT CHARACTERISTICS

Relcer Gel (Aluminum Hydroxide, Magnesium Hydroxide, Simethicone and Deglycyrrhizinated Liquorice Gel)

1. NAME OF THE MEDICINAL PRODUCT

Relcer Gel (Aluminum Hydroxide, Magnesium Hydroxide, Simethicone and Deglycyrrhizinated Liquorice Gel)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Aluminium Hydroxide Gel USP
Equivalent to Aluminium Hydroxide…….365 mg
Magnesium Hydroxide Paste USP
Equivalent to Magnesium Hydroxide…….80 mg
Simethicone USP……...100 mg
Deglycyrrhizinated Liquorice
Equivalent to Liquorice……..400 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antacid therapy in gastric and duodenal ulcer, gastritis, dyspepsia, heartburn and gastric hyperacidity.

4.2 Posology and method of administration

For oral administration

Adults
5-10 ml taken twenty minutes to one hour after meals and at bedtime or as required. It can be taken with water or milk if required.

Elderly
Normal adult dose is appropriate.

Special populations
Pediatric population
Not recommended in children and adolescents under 18 years of age due to lack of adequate data.

Renal impairment
Not recommended in patients with renal impairment.

Hepatic impairment
No dose adjustment is required in patients with hepatic impairment.

4.3 Contraindications
Should not be used in patients who are hypersensitive to any of the active substance or excipients and are severely debilitated or suffering from kidney failure or hypophosphatemia or if there is severe abdominal pain and/or the possibility of bowel obstruction.

4.4 Special warnings and precautions for use
Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product 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 phosphorous 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 encephalopathy, dementia, microcytic anemia or worsen dialysis-induced osteomalacia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders.

Liquorice medication is not recommended to be used in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of liquorice.

Concomitant use with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance is not recommended.

<u>Paediatric population</u>
In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
This product contains methyl paraben, propyl paraben and sodium benzoate; these may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

This product should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

Aluminium-containing antacids are known to interfere with the absorption of drugs notably H_2 antagonists, atenolol, bisphosphonates, chloroquine, chlorpromazine, cefdinir, cefpodoxime, ciprofloxacin, cyclines, dasatinib monohydrate, diflunisal, digoxin, dexamethasone, eltrombopag olamine, elvitegravir, ethambutol, fluoroquinolones, glucocorticoids, hydroxychloroquine, indomethacin, iron salts, isoniazid, ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, phenotiazine neuroleptics, penicillamine, propranolol, raltegravir potassium, rifampicin, rilpivirine, riociguat, rosuvastatin, sodium fluoride, antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, tetracyclines, and vitamins.

With the integrase inhibitors (dolutegravir, raltegravir, bictegravir) the product should be avoided (please refer to their SmPC for dose recommendations).

As a precaution, staggering the administration times of any orally administered drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine.

Polystyrene sulphonate

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks 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).

Quinidine:

Concomitant use of aluminium products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.

Tetracycline:

Because of the aluminium content, this product should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

Citrates:

Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.
Liquorice may counteract antihypertensive action of prescribed medications.

Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.

4.6 Pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use of this product during pregnancy and lactation is not recommended.

Pregnancy

The safety of this product in pregnancy has not been established. No conclusions can be drawn regarding whether or not this product is safe for use during pregnancy. This product should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the feotus.

Lactation

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

Simethicone is not absorbed from the gastrointestinal tract.

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of the breastfeeding woman to aluminium hydroxide, magnesium hydroxide and simethicone is negligible.

In the absence of sufficient data, the use of this product during lactation is not recommended.

Fertility

No fertility data is available.

4.7 Effects on ability to drive and use machines

No studies on the effect of this product on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Aluminum Hydroxide, Magnesium Hydroxide, Simeticone

The following CIOMS frequency rating is used, when applicable: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data)

Immune system disorders:

Frequency not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders:

Gastrointestinal side effects are uncommon.

Uncommon: diarrhoea or constipation

Frequency not known: Abdominal pain

Injury, poisoning and procedural complications:

Frequency not known: Hyperaluminemia (related to Aluminium component).

Metabolism and nutrition disorders:
Very rare: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment.

Frequency not known: Hyperaluminemia

Hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low phosphorus diets, which may result in increased bone resorption, hypercalciuria, osteomalacia.

Deglycyrrhizinated liquorice No data available.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions via national regulatory portal or systems.

4.9 Overdose
Serious symptoms are unlikely following overdosage.

Discontinue medication and correct fluid deficiency if necessary.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk.

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of intravenous calcium gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

Cases of overdose have been reported with prolonged use (more than 4 weeks) and/or intake of high amount of liquorice, with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulants.
ATC Code: A02A F02.

Dried aluminium hydroxide gel	- antacid
Magnesium Hydroxide	- antacid
Simethicone	- antifoaming agent/antiflatulent

Deglycyrrhizinated liquorice - demulcent

This product is a balanced mixture of two antacids, an antiflatulent/antifoaming agent simethicone and demulcent agent deglycyrrhizinated liquorice.

The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea. Deglycyrrhizinated liquorice has demulcent effects which help in relieving minor inflammations of the gastrointestinal tract, abdominal pain and burning sensation in the stomach.

5.2 Pharmacokinetic properties

Aluminium hydroxide and magnesium hydroxide

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastrointestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

Simethicone

Simethicone is not absorbed from the gastrointestinal tract.

Deglycyrrhizinated liquorice No relevant data available.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Guar, Sorbitol Solution 70%, Sodium benzoate, Sodium Citrate, Menthyl Hydroxy Benzoate, Propyl Hydroxy Benzoate, Sodium Hydroxide, Saccharin Sodium, Banana Flavour, Mentha Oil, Bronopol, Sodium Hypochlorite Solution, Purified Water.

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 25°C. Protect from light. Do not freeze.

6.5Nature and contents of container and special equipment for use, administration or implantation

A printed carton containing a leaflet and amber coloured labeled sealed PET bottle containing cream coloured, viscous suspension with banana and peppermint flavour with 10 ml measuring cup.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product should be disposed of in accordance with local requirements.

Shake well before use.

7. APPLICANT/SUPPLIER

Glenmark Pharmaceuticals Limited
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai road, Mumbai – 400 026. Maharashtra. India.

Manufactured at:
Glenmark Pharmaceuticals Ltd.
Plot no. E-37,39, D-Road, M.I.D.C., Satpur, Nashik-422 007, Maharashtra,
India

8. WHO PREQUALIFICATION REFERENCE NUMBER

Not Applicable

9. DATE OF AUTHORISATION / RENEWAL OF AUTHORISATION

07-Aug-1989

10. DATE OF REVISION OF THE TEXT November 2025

Reference list

- Natural health product deglycyrrhizinated licorice oral, Canada
- Community herbal monograph on Glycyrrhiza glabra L. and/or Glycyrrhiza inflata Bat. and/or Glycyrrhiza uralensis Fisch., radix, EMA/HMPC/571119/2010, 22 May 2012.
- Summary of product characteristics of Maalox 175mg/200mg Oral Suspension, Opella Healthcare UK Limited, January 2025
- Summary of Product Characteristics of Maalox Plus suspension, Opella Healthcare UK Limited, December 2023