INFORMATION FOR THE PHYSICIAN

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

1. NAME OF THE MEDICINAL PRODUCT

Relcer (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

Excipients with known effect:
Methyl Paraben, Propyl Paraben, Sorbitol, Sodium Benzoate
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomatic relief in the treatment of peptic ulcer, gastro-esophageal reflux disease (GERD), gastritis, oesophagitis and dyspeptic conditions associated with 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.

Renal impairment

Not recommended in patients with renal impairment.

Hepatic impairment

No dose adjustment is required in patients with hepatic impairment.

4.3 Contraindications

In patients who are hypersensitive to any of the active substance or excipients and are severely debilitated or suffering from kidney failure or hypophosphatemia.

4.4 Special Warnings and Precautions for Use

General

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).

Aluminium hydroxide and magnesium hydroxide

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 dementia, microcytic anemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

Deglycyrrhizinated liquorice
Because of lack of long-term term safety studies, deglycyrrhizinated liquorice should be avoided by children, pregnant women and nursing mothers.

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

4.5 Interaction with other medicinal products and other forms of interaction

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

Aluminium hydroxide and magnesium hydroxide
Aluminium-containing antacids may prevent the proper absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin.

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).

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.

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

4.6 Fertility, Pregnancy and lactation

Pregnancy
The safety of this combination in pregnancy has not been established. There is insufficient data to support the safety of deglycyrrhizinated liquorice in pregnancy.

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.

Simeticone is not absorbed from the gastrointestinal tract.

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

There is insufficient data to support the safety of deglycyrrhizinated liquorice in lactation.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Aluminium hydroxide and magnesium hydroxide
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

Metabolism and nutrition disorders:
Very rare: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment
Frequency not known: hypermagnesemia and 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.

Simethicone

No data available

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.

4.9 Overdose

Serious symptoms are unlikely following overdosage.

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.

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
Simeticone	- antifoaming agent/antiflatulent
Deglycyrrhizinated liquorice	- demulcent

This product is a balanced mixture of two antacids, an antiflatulent/antifoaming agent simeticone and antiulcer 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. The antacids are balanced such that gastrointestinal side effects (constipation and diarrhoea) are minimal. Simethicone is a surface active substance (surfactant) which changes the surface tension of intestinal mucus resulting in elimination of gas, air or foam from the gastro-intestinal tract. Deglycyrrhizinated liquorice has demulcent effects which help in relieving 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 in the body. It is excreted unchanged in the faeces.

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

D.G.L. Powder 10:1, Guar, Sorbitol Solution 70%, Sodium Benzoate, Sodium Citrate, Methyl Hydroxy Benzoate, Propyl Hydroxy Benzoate, Sodium Hydroxide, Saccharin Sodium, Banana Flavour, Mentha Oil, Bronopol, Sodium Hypochlorite Solution and Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life: 48 months from the date of manufacturing.

6.4 Special precautions for storage: Store below 30°C. Protect from freezing and light.

6.5 Nature and contents of container: A printed carton containing a leaflet and amber coloured labelled sealed PET bottle with 10ml measuring cup, containing a cream coloured, viscous suspension with banana and peppermint flavor.

6.6 Special precautions for disposal and other handling: Keep all medicines out of reach of children.

7. MARKETING AUTHORISATION HOLDER

Glenmark Pharmaceuticals Limited, B/2, Mahalaxmi Chambers,
22 Bhulabhai Desai road, Mahalaxmi, Mumbai – 400026.

8. MARKETING AUTHORISATION NUMBER(S)

NKD/ 803

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14-12-2017

10. DATE OF REVISION OF THE TEXT

Aug 2019