SUMMARY PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Trade Name : DISOGEL TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Chewable tablet contains:
Deglycyrrhizinated Liuquorice 400mg,
Dried Aluminium Hydroxide 250mg,
Magensium Hydroxide 250mg,
Simethicone 40mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DISOGEL TABLETS is indicated in,
Peptic ulcer, Duodenal ulcer, Gastric ulcer, Hyperacidity, Dyspepsia, Heartburn in pregnancy, Gastritis, Flatulence.

4.2 Posology And method of Administration:

1 to 2 tablets between meals or as directed by the physician.

4.3 Contraindication

Known idiosyncrasy to any of the ingredients.
Should not be used in patients who are severely debilitated or suffering from kidney failure
Use in severely debilitated patients or in those suffering from kidney failure.
Use in patients who are allergic to any of the ingredients

4.4 Special warning and precautions for use

Do not use this product except under the advice and supervision of a physician if you have kidney disease. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.
Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminum are absorbed from the gastrointestinal tract and renal excretion of aluminum is impaired in renal failure. Aluminum is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminum is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminum are ingested orally by patients with impaired renal function.
Aluminum forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

4.5 Interaction with other medicinal products and other forms of interactions

Do not take these products within two hours of another medication because the effectiveness of the other medication may be altered.
Antacids may interfere with other drugs by increasing the gastric pH, by adsorbing or binding drugs to their surface or by increasing urinary pH.
Oral tetracyclines: Antacids should not be taken within three to four hours of tetracyclines.
Oral Iron Preparations: Antacid doses should be spaced as far apart as possible from doses of oral iron preparations.
Fluoroquinolones: Concurrent use of aluminum and magnesium-containing antacids and fluoroquinolones is not recommended because the absorption of the fluoroquinolones may be reduced.
When antacids are used concurrently with ciprofloxacin or norfloxacin, patients should be observed for signs of crystalluria and nephrotoxicity.
Ketoconazole: Patients should be advised to take antacids at least three hours after ketoconazole.
Mecamylamine: methenamine, sodium polystyrene sulfonate resin: Concurrent use is not recommended.
Tetracyclines (medicine for infection) taken by mouth—Use with antacids may decrease the effects of both medicines; Disogel should not be taken within 3 to 4 hours of tetracyclines
Methenamine: Antacids may decrease the effects of ketoconazole or methenamine; these medicines should be taken 3 hours before the antacid.

4.6 Pregnancy and lactation

Category B: Either animal-reproduction studies have shown no harm to fetus but studies in women have not been done/ are not available or adverse effect shown in animals is not shown during studies in women.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Gastrointestinal: Constipation; diarrhea; nausea; vomiting; intestinal obstruction.

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 asked to report any suspected adverse reactions via

Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

Massive overdosage should be treated by gastric lavage and by catharsis with castor oil or other laxatives not containing magnesium. Should symptoms of magnesium intoxication be present, calcium gluconate should be administered intravenously.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

They act by neutralising the hydrochloric acid produced by the stomach and thus reducing gastric and duodenal irritation.

5.2 Pharmacokinetic Properties

Deglycyrrhinized liquorice

Metabolic studies of Deglycyrrhizinised liquorice (2.28g/day for 21 days) have been performed in two women with gastric ulcer. In neither patient were there any appreciable changes in weight, blood pressure, serum levels or external balance of sodium, potassium and chloride. The only marked metabolic change was positive nitrogen balance in each patient.

Except for the chloride and sulphates, magnesium compounds are not absorbed, due to their intrinsic insolubility. However, the oxides, hydroxides and trisilicates are converted by acid gastric juice into soluble magnesium chloride, which is absorbed.

The concentration in a skeleton represents an exchangeable fluid and plasma is about 15 and 0.75-1.1 mmol.1-1 respectively. One third is protein bound and the remainder is ionized. It rapidly diffuses into all other tissues. Small and clinically irrelevant amounts are excreted in milk. The major excretory pathway of magnesium is renal and both oral and intravenous loads are rapidly eliminated. In renal impairment there may be accumulation of magnesium.

DGL is devoid of salt retaining property but possesses anti-spasmodic activity. The mechanism of action of DGL is not known. Experiments in animals have shown it to have an antispasmodic effect on the spontaneous activity of ileum of rabbit, to inhibit motility induced by vagal stimulation in the isolated stomach of the guinea pig and to reduce the gastric acid secretion resulting from vagal stimulation or intravenous pengastrin. However, a protective effect against stomach ulcer formation in rats has been demonstrated at doses, which have no effect on gastric acid secretion.

Various possible modes of action has been proposed and these include the effects on mucus production, mucosal regeneration, local blood flow and mucosal fluid transport.

Aluminium hydroxide

The insoluble aluminium compounds that constitute aluminium hydroxide are slowly but perhaps incompletely solublised in the stomach to form aluminium chloride. Some absorption of aluminium from the soluble salt occurs in the gastrointestinal tract with some excretion in the urine.

Some unabsorbed aluminium hydroxide combines with phosphates present in the gut to form insoluble aluminium phosphates and some forms other insoluble salts such as carbonates and salts of fatty acids; all these are excreted in the faeces.

The rate of neutralization of acid by aluminium hydroxide is considerably slower than that achieved by magnesium salts. Even the most reactive aluminium hydroxide cannot raise the pH much above 4.5. Aluminium hydroxide also acts as an adsorbent of pepsin. At a pH above 3.0, aluminium hydroxide adsorbs pepsin, which is released when the pH falls below 3. Aluminium salts also relax gastrointestinal smooth muscle and delay gastric emptying. This contributes to the constipating effect of aluminium hydroxide. Aluminium is said also to stimulate mucus secretion, which may help to promote a mucosal barrier to acid. Aluminium hydroxide interferes with phosphate absorption by forming insoluble aluminium phosphate in the gut. It may also inhibit the absorption of fluoride ions and binds some fatty acids and proteins in the gut.

Aluminium hydroxide on its own may be a useful antacid in those patients prone to diarrhoea, because of the constipating effect aluminium hydroxide. Small quantities of aluminium are absorbed from aluminium hydroxide. After administering 2.2g of aluminium as 120ml of aluminium hydroxide gel over three days, a doubling of plasma aluminium concentration has been observed. This is usually only a problem in patients with renal insufficiency.

The data on buffering capacity are confusing because of the variables involved, including gastric emptying and the pH to which the antacid is titrated. However, data based on clinical trials indicate that doses of 200 mmol per 24 in six doses will produce healing of ulcer equivalent to cimetidine.

Simethicone

Simethicone is an anti-flatulent, which relieves flatulence by dispersing and preventing the formation of mucus surrounded gas pockets in the gastrointestinal tract.

Simethicone acts in the stomach and intestines to change the surface tension of gas bubbles, enabling smaller bubbles to join together into bigger bubbles. In this way it is believed that gas can be eliminated more easily by belching or passing flatus.

5.3 Preclinical Safety Data

No relevant data

6. PHARMACEUTICAL PARTICULARS

List of excipients

Dextrose monohydrate BP

Saccharine Sodium BP

Citric acid (Monohydrate) BP
Sucrose BP
(Sodium methyl hydroxy benzoate) Sodium Methyl Paraben BP
(Sodium propyl hydroxy benzoate) Sodium Propyl Paraben BP
Sorbitol solution BP
Mannitol BP
Purified Talc BP
Magnesium Stearate BP
Peppermint oil BP
Trusil chocolate flavour IHS
Chocolate brown colour HIS

6.2 Incompatibilitis

None

6.3 Shelf life

60 months from the date of manufacture.

6.4 Special precautions for storage

Do not store above 30°C, protected form moisture

6.5 Nature and contents of container

The immediate container of the product is a strip pack. 10 strips of 10 Tablets each are placed in one printed duplex board cartons.

6.6 INSTRUCTIONS FOR USE AND HANDLING

Route of Administration: Oral

Dosage: 1 to 2 tablets between meals or as directed by the physician

Direction: Tablet should be chewed before being swallowed

7. MARKETING AUTHORISATION HOLDER

Concept Pharmaceutical Ltd.
Khasra No. 104, Asaf Nagar,
Behind Hotel Godawari,
Roorkee – 247667 (U.K),
Tel. No.: 09568400023
INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

H2021/CTD6582/12457

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

2021 September 01

10. DATE OF REVISION OF THE TEXT:

22/08/2026