SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Moxal Chewable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Chewable tablet contains:

Item No.	Material Name	Scale (mg/Tab)
	Active Ingredients:	
1.	Aluminium Hydroxide Dried Gel	405.00
2.	Magnesium Hydroxide Powder	100.00

3. PHARMACEUTICAL FORM

Chewable Tablets
Description: White to off-white, round, flat faced bevel edged mottled slightly pitted surface chewable tablets.
Marking: Face one: GPI
Face two: Score-line

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Moxal is used for the relief of the symptoms of dyspepsia.

4.2 Posology and method of administration

The route of administration is oral.

Recommended Dosage
Adults: 1-2 tablets chewed 4 times daily, taken 20 minutes to 1 hour after meals and at bedtime, or as directed by the physician. A maximum of 8 tablets in a 24 hour period should not be exceeded, nor should the maximum dose continue for more than 2 weeks except under the direction of the physician.
Children: Not recommended

4.3 Contraindications

- Use in severely debilitated patients or in those suffering from kidney failure.
- Use in patients who are hypersensitive to the active ingredients or to any of the excipients.

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, infants less than 2 years, 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-phosphorus diets or in infants less than 2 years, 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. Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with caution in patients with advance renal disease.
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.
The prolonged use of antacid in patients with renal failure should be avoided.
Care should be observed if used by diabetics because of the sugar content of the tablet.
Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis because it has been shown that aluminium may be involved in porphyrin metabolism abnormalities.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
Pronlonged use with antacids may mask symptoms of more serious diseases, such as gastrointestinal ulceration or cancer.

4.5 Interaction with other medicinal products and other forms of interaction

This product may form complexes with certain drugs, e.g. tetracyclines, digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.
Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.
Concomitant use with quindines may increase the serum levels of quinidine and lead to quinidine overdosage.
Aluminium-containing antacids may prevent the proper adsorption of H2 antagonists, atenolol, cefdinir, cefpodoxime, chloroquine, cyclines, difunisal, digoxin, diphosphonates, ethambutol, fluroquinolones, sodium fluorure, glucocorticoids, indometacine, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics phenothiazines, penicillamine, propranolol, iron salts.Staggering the administration times of the interacting drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones) will often help avoid undesirable drug interactions.

Polystyrene sulfonate (Kayexalate)
Caution is advised when used concomitantly with polystyrene sulfonate (Kayexalate) 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.

4.6 Pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician.
Because of the limited maternal absorption when used as recommended, aluminium hydroxide and magnesium salts combinations are considered as compatible with lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects are uncommon at recommended doses

Immune system disorders
Not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions
Gastrointestinal disorders
Uncommon: diarrhoea or constipation (see Section 4.4 Special warnings and precaution s for Use)
Not known: abdominal pain
Metabolism and nutrition disorders
Very rare: hypermagnesemia including observations after prolonged administration of magnesium hydroxide to patients with renal impairment.
Not known:

- hyperaluminemia,
- hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets or in infants less than 2 years, which may result in increased bone resorption, hypercalciuria, osteomalacia (see Section 4.4 Special warnings and precaution s for Use).

Healthcare professionals are asked to report any suspected adverse reactions via:
Pharmacovigilance and Medical Device Section
Drug Department - U.A.E M.O.H
Hotline: 80011111
Email: pv@moh.gov.ae
P.O. Box: 1853 Dubai U.A.E.

4.9 Overdose

Signs and symptoms
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 (see Section 4.4 Special warnings and precautions for Use)

Management

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

Serious symptoms are unlikely following overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Moxal is a balanced mixture of two antacids: aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a fast-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts may cause diarrhoea.

5.2 Pharmacokinetic properties

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 gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

5.3 Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive Ingredients:

1. Mannitol
2. Glucose monohydrate
3. Sucrose
4. Saccharin sodium
5. Povidone (PVP K-90)
6. Sorbitol powder
7. Dextrates NF
8. Talc fine powder
9. Magnesium stearate
10. Mint dry flavour
11. Purified water*

* Evaporates during process, not appearing in the final products.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C, in a dry place

6.5 Nature and contents of container

- 10 tablets in a blister, 3 blisters packed in a printed carton along with a leaflet.
- 100 x 10 tablets in a blister, 3 blisters packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER

Gulf Pharmaceutical Industries - Julphar
Digdaga, Airport Street.
Ras Al Khaimah - United Arab Emirates.
P.O. Box 997
Tel. No.: (9717) 2 461 461
Fax No.: (9717) 2 462 462

8. MARKETING AUTHORISATION NUMBER(S)

05954/07806/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

May 21, 2021

10. DATE OF REVISION OF THE TEXT

16. April. 2019