SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 **Brand Name** : Antagit-DS Gel (Orange Flavour)

1.2 **Generic Name** : Alumina, Magnesia and Simethicone Oral Suspension

1.3 **Strength** : Aluminium hydroxide 400 mg, Magnesium hydroxide 400 mg Simethicone 50 mg/5 ml

1.4 **Pharmaceutical Form** : Oral Suspension

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5 ml contains:

Dried Aluminium Hydroxide (Added as Aluminium Hydroxide Paste)	BP	400 mg
Magnesium Hydroxide (Added as Magnesium Hydroxide Paste)	BP	400 mg
Simethicone	USP	50mg
Flavoured base		q.s.

Colour: Sunset Yellow FCF

3. PHARMACEUTICAL FORM

Oral Suspension

Orange coloured, flavoured, palatable suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Flatulence, Hyperacidity, Peptic ulcer, Duodenal ulcer, Dyspepsia, Heart burn, Gastritis, Hiatal hernia and Gaseous distension.

4.2 Posology and method of administration

Adult: 5–10 ml 2 to 3 times a day, to be taken after meals and at bedtime, as prescribed by the Physician.

4.3 Method of administration

Oral

4.4 Contraindications

It should not be used in patients who are hypersensitive to any of the active substances, patients with chronic renal disease and dialysis because Magnesium retention may occur in such patients & also may cause hypophosphataemia.

4.5 Special warnings and precautions for use

Aluminium Hydroxide may cause constipation & Magnesium Hydroxide 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. In patients with renal impairment, plasma levels of both Aluminium & 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. In young children the use of Magnesium Hydroxide can produce a

hypermagnesemia, especially if they present renal impairment or dehydration.

4.6 Drug Interaction

It should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour. Aluminium containing antacids may prevent the proper absorption of drugs such as Tetracyclines, vitamins, Ciprofloxacin, Ketoconazole, Hydroxychloroquine, Chloroquine, Chlorpromazine, Rifampicin, Cefdinir, Cefpodoxime, Levothyroxine, Rosuvastatin. Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine. Urine alkalinisation secondary to administration of Magnesium Hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.7 Pregnancy and lactation

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of Aluminium Hydroxide and Magnesium Hydroxide combinations are expected to be excreted into breast milk. Simethicone is not absorbed from the gastrointestinal tract. No effect on the breastfed newborn/infant is anticipated since the systemic exposure of the breast-feeding woman to Aluminium Hydroxide, Magnesium Hydroxide and Simethicone is negligible.

4.8 Effects on ability to drive and use machines

None reported

4.9 Side effects

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:** 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

4.10 Overdose & Treatment

Serious symptoms are unlikely following overdosage. Reported symptoms of acute overdose with Aluminium Hydroxide and Magnesium Hydroxide 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 IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacid-Antiflatulent

ATC code: A02AF (Antacids with antiflatulents)

Aluminium Hydroxide: Is partly Aluminium Hydroxide and partly Aluminium Oxide hydrated to a variable extent. It reacts with Hydrochloric Acid in stomach forming Aluminium Chloride. Aluminium Hydroxide is insoluble; hence the fraction of excess remains in the stomach shall exert a sustained effect. Gastric pH does not rise above the level which will inhibit conversion of pepsinogen to pepsin. It is also a demulscent. Wet particles of Aluminium Hydroxide are somewhat adhesive and this helps in forming the protective coat over the ulcer.

Magnesium Hydroxide: Reacts with gastric Hydrochloric Acid forming Magnesium Chloride. It is also a long acting antacid with high acid neutralizing capacity.

Simethicone: Is an anti-foaming agent. It acts by changing the surface tension of gas bubbles thereby causing them to coalesce, thus facilitating the elimination of gas. Accordingly it provides the relief from abdominal distension and dyspepsia.

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. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur. Simethicone is physiologically inert and not systemically absorbed, also not metabolize & is excreted unchanged in the feces.

5.3 Preclinical safety data

Not known

6. PHARMACEUTICALPARTICULARS

6.1 List of Excipients:

SN	Ingredients	Spec.
1.	Sodium Methyl Hydroxybenzoate (Sodium Methylparaben)	BP
2.	Sodiu Propyl Hydroxybenzoate (Sodium Propylparaben)	BP
3.	Bronopol (Bronidiol)	BP
4.	Carmellose Sodium (C.M.C. Sodium (HVP Trans.)	BP
5.	Saccharin Sodium	BP
6.	Sodium Citrate	BP
7.	Citric acid Monohydrate	BP
8.	Liquid Sorbitol (Sorbitol Solution 70%)	BP
9.	Sorbic Acid	BP
10.	Sodium Hydroxide	BP
11.	Lake Sunset Yellow	IH
12.	Essence Orange Sweet	IH
13.	Essence Milk No. 1	IH
14.	Purified Water	BP

6.2 Incompatibilities

None reported

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

Do not freeze. Protect from light. Keep out of reach of children. Keep container tightly closed. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

a. 100 ml. in a clear PET bottle in an inner carton.
b. 170 ml. in a clear PET bottle in an inner carton.
c. 350 ml. in a clear PET bottle.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING
LEBEN LABORATORIES PVT. LTD.

Business Address:

RO & Works : Plot No. L-4 & L-15, Phase-III, MIDC,
AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2258328, 2259401/02/03 & Fax: 2258371
E-mail - export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion,
70, Trinity Street, Near Metro Cinema, MUMBAI–
400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 2207-5303
E-mail - mumbai@lebenlab.com
Country : INDIA

8. MARKETING AUTHORISATION NUMBER
06579/07530/REN/2020

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
a) Date of latest renewal: Oct 14, 2021

10. DATE OF REVISION OF THE TEXT
01/01/2023

11. DOSIMETRY (IF APPLICABLE)

Not applicable

12. INSTRUCTIONS FOR PREPARATION OFRADIOPHARMACEUTICALS (IF APPLICABLE)

Not applicable