SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Antagit-DS Gel**
1.2 Generic Name : **Alumina, Magnesia & Simethicone Oral Suspension**
1.3 Strength : **400mg + 400mg + 50mg /5ml**
1.4 Pharmaceutical Form: **Oral Suspension**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5ml contains:

Dried Aluminium Hydroxide (added as a paste)	BP	400mg.
Magnesium Hydroxide (added as a paste)	BP	400mg.
Simethicone	USP	50mg.
Flavoured base		q.s.

3. PHARMACEUTICAL FORM

Oral Suspension; Pink coloured, flavoured palatable suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antagit DS gel (Alumina, Magnesia & Simethicone Oral Suspension) is indicated for treatment of hyperacidity, peptic ulcer, duodenal ulcer, dyspepsia, heart burn, gastritis, hiatal hernia and gaseous distension.

4.2 Posology and method of administration

5–10 ml (1 to 2teaspoonful), 2 to 3 times daily, after food or as prescribed by the Physician.

4.3 Contraindications:

It is contraindicated in patients with chronic renal disease and dialysis because magnesium retention may occur in such patients.

4.4 Special warnings and special precautions for use:

The antacids are usually recommended atleast one hour before or after other medication.

4.5 Interaction with other FPPs and Other forms of 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 administrat ion of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Pregnancy and lactation

Antagit DS Gel 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 are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simethicone is negligible.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Aluminium hydroxide: Prolonged used by person ingesting a diet low in phosphate may cause osteomalacia and proximal myopathy. Aluminium hydroxide may hinder absorption of concurrently administered drug like Tetracyclines. Magnesium Hydroxide: Although classified as a non systemic antacid , about 5to 10% of magnesium can be absorbed causing systemic alkalosis, neurological manifestation in case of renal insufficiency.

4.9 Overdose

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. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacid

Mechanism of action:

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 magne-sium 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

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Ingredients	Spec.
Sodium Methyl Hydroxybenzoate	BP
Sodium Propyl Hydroxybenzoate	BP
Bronopol (Bronidiol)	BP
Carmellose Sodium	BP
Saccharin Sodium	BP
Sodium Citrate	BP
Citric acid Monohydrate	BP
Liquid Sorbitol (Sorbitol Sol.70%)	BP
Sorbic Acid	BP
Sodium Hydroxide	BP
Lake Erythrosine	IH
Essence Peppermint-10211	IH
Menthol	BP
Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30^0C. Protect from light. Keep out of reach of children. Keep container tightly closed. Shake well before use.

6.5 Nature and contents of container

170ml in clear PET bottle in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKET AUTHORIZATION

06469/07163/REN/2019

9. DATE OF AUTHORIZATION

Aug 12, 2021