

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SALOGEL-O SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Medicinal product contains Salogel-O suspension

a. Each 15ml of the suspension contains the following ingredients

Active Ingredient

Alginic Acid B.P	200mg
Magnesium Hydroxide B.P	250mg
Dried Aluminium Hydroxide B.P	250mg
Magnesium Trisilicate B.P	250mg
Simethicone B.P	125mg
Oxethazaine B.P	30mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL Form

Pharmaceutical Dosage form of the product: Suspension

Description: A pink coloured, peppermint flavoured suspension.

Route(s) of administration: Oral

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Salogel-O acts as antacid in non-ulcer dyspepsia and is used for the symptomatic relief of Gastritis, hyperacidity associated with peptic ulceration, relief from ulcer, reflux oesophagitis, heartburn and flatulence

4.2 Posology and method of administration

Taking this medicine

- Shake well before use
- Take this medicine by mouth

Adults including the elderly

- ☐ Take three 5ml spoonfuls (15mls) 2 - 3 times each day
- ☐ Take 1 hour before meals or 3 hours after meals and at bedtime
- ☐ Alternatively, take as directed by your doctor or pharmacist.

Children aged 12 to 18 years

- Take three 5ml spoonfuls (15mls) 2 - 3 times each day

- Take 30 minutes to 1 hour before meals or 3 hours after meals and at bedtime
 - Alternatively, take as directed by your doctor or pharmacist.

Children aged 2 to 12 years

- Not recommended

If the symptoms do not go away, talk to your doctor or pharmacist.

4.3 Contraindications

Antacids should not be used in patients who are severely debilitated or suffering from renal insufficiency, or if there is severe abdominal pain and/or the possibility of bowel obstruction.

The use of aluminum-containing antacids (except those containing aluminum phosphates) is contraindicated in patients with hypophosphatemia due to the phosphate binding properties of aluminum salts. The use of magnesium-containing antacids is contraindicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesemia.

The use of aluminum- or magnesium-containing antacids is contraindicated in patients with symptoms of appendicitis since these products may increase the danger of perforation or rupture due to their constipating or laxative effects.

Should be used with caution in patients with volume depletion, gastrointestinal obstruction or upper gastrointestinal bleeding.

4.4 Special warnings and precautions for use

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.

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

4.5 Interaction with other medicinal products and other forms of interaction

The rate and/or extent of absorption of many drugs may be increased or decreased when they are used concurrently with aluminum-magnesium hydroxide containing antacids. Therefore, as a general rule, medication should not be taken within 1 to 2 hours of an antacid, if possible. Antacids are known to interfere with the absorption of certain drugs including budesonide, aspirin, barbiturates, tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, ACE inhibitors and β - blockers.

An increase in the plasma level of quinidine and possible toxicity may result if alkalization of the urine occurs during antacid therapy.

Antacids may interfere with drugs by increasing the gastric pH altering disintegration, dissolution, solubility, ionization and gastric emptying time.

Absorbing or binding drugs to their surface resulting in decreased bioavailability such as tetracycline.

Urinary excretion of certain drugs may also be affected.

Antacids containing magnesium salt may increase absorption of Sulphonylureas and thereby increases the hypoglycemic effect.

4.6 Pregnancy and lactation

The safety of Salogel-O in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines None stated.

4.8 Undesirable 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 Metabolism and nutrition disorders Frequency not known:

Hypermagnesemia

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.

4.9 Overdose

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.

Treatment of magnesium overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

5. Pharmacological properties

5.1 Pharmacodynamics' properties

Salogel-O is a balanced mixture of two antacids. Aluminium hydroxide is a slow acting antacid and Magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. The effect is balanced by the effect of magnesium hydroxide, which in common with other magnesium salts, may cause diarrhea. Gastro-intestinal side effects are thus rare with Salogel-O and this makes it especially suitable when long term therapy necessary.

Simethicone (activated) either alone or with antacid mixture acts as an antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily suitable when long term therapy is necessary.

Alginic acid is combined with antacid to encourage adherence of the mixture to the mucosa.

Alginate as mucosal protectant is useful in reflux oesophagitis.

Oxetacaine is added to the formulation to act as a local anesthetic. This will further assist in the relief of symptoms associated with ulcer, Gastritis, Reflux Oesophagitis, etc.

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.

5.3 Preclinical safety data

No relevant data

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol (E420)

Sodium citrate (E331)

Saccharin sodium

Xanthan gum (E415)

Propylene glycol (E1520)

Methyl paraben (E219)

Propyl paraben (E217)

Peppermint Oil (E415)

Polysorbate 80

Erythrosine Red (E127)

Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

200 mL amber coloured round glass bottle sealed with 25 mm Aluminium PP cap along with 10 mL measuring cup, packed in a carton with package insert.

6.6 Special precautions for disposal and other handling

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Marketing Authorization Holder and Manufacturing Site Address

Salom Pharmaceuticals Limited
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8. Marketing Authorization Number

FDA/SD.175-7451

9. Date of First Authorization or renewal

8th May,2024

10. Date of revision of the text

31/07/2025