# SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

## 1. NAME OF THE MEDICINAL PRODUCT

**CORASIL (**Alumina, Magnesia and Simethicone Oral Suspension)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 50 mg Simethicone, 250 mg Magnesium Hydroxide, and 250 mg Dried Aluminum Hydroxide gel

*Excipient(s) with known effect:*

Sorbitol Solution 70%

Colour: Erythrosine

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Suspension

Pink colored, syrupy suspension with peppermint odor.

## 4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

The symptomatic relief of:
1. Dyspepsia.
2. Heartburn.
3. Flatulence

4.2 Posology and Method of Administration:
For oral administration:

Adults

5-10 ml taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5ml t.d.s.

Elderly

The normal adult dose is appropriate.

4.3 Contraindication:

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia.

4.4 Special Warnings and Precautions for Use:

Aluminum 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, or the elderly.

Aluminum 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-phosphorous diets, may lead to phosphate depletion (due to aluminum-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.

In patients with renal impairment, plasma levels of both aluminum and magnesium increase. In these patients, a long-term exposure to high doses of aluminum and magnesium salts may lead to encephalopathy, dementia, microcytic anemia or worsen dialysis-induced osteomalacia.

Aluminum hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction:

CORASIL SUSPENSION should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

aluminum-containing antacids may prevent the proper absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, $H_2$ antagonists, atenolol, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol,

fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine, propranolol and iron salts.

Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine.

Polystyrene sulphonate

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminum hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminum hydroxide).

Quinidine:

Concomitant use of aluminum products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.

Tetracycline:

Because of the aluminum content, CORASIL SUSPENSION should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

Citrates:

Aluminum hydroxide and citrates may result in increased aluminum levels, especially in patients with renal impairment.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Pregnancy and Lactation:

The safety of Corasil Suspension in pregnancy has not been established.

Pregnancy:

There are no available data on Corasil Suspension use in pregnant women. No conclusions can be drawn regarding whether or not Corasil Suspension is safe for use during pregnancy. Corasil Suspension should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the feotus.

Lactation:

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of aluminum hydroxide and magnesium salt 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 aluminum hydroxide, magnesium hydroxide and simethicone is negligible.

4.7 Effects on Ability to Drive and Use Machines:

None stated.

4.8 Undesirable Effects:

The following CIOMS frequency rating is used, when applicable:
Very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).
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
Injury, poisoning and procedural complications:\
Frequency not known:
Hyperaluminemia (related to Aluminium component):
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.

4.9 Overdose:

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminum 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.

Aluminum 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: Drugs for acid related disorders; Antacids with antiflatulents,

ATC Code: A02AF02

Dried aluminum hydroxide gel - antacid

Magnesium Hydroxide - antacid

Simeticone - antifoaming agent/antiflatulent

Corasil Suspension is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simeticone. The two antacids are magnesium hydroxide which is fast acting and aluminum hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminum hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea.

5.2 Pharmacokinetic Properties:
None stated.

5.3 Preclinical Safety Data:

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

## 6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Erythrosine
Levomenthol
Peppermint
Bronopol BP
Polysorbate 80 (Tween 80)

Purified water
Sodium saccharin
Colloidal anhydrous silica
CMC Sodium HVP
Liquid Sorbitol (non – Crystallising)
Sodium Methyl hydroxybenzoate
Sodium Propyl hydroxybenzoate
Sodium Benzoate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life:

24 Months

6.4 Special Precautions for Storage

Store below $30^0$C. Protect from Light.

Keep medicine out of reach of children.

6.5 Nature and Contents of Container:

Primary Packing: 100 ml & 200 ml of Amber coloured Pet bottle

Secondary Packing: Such one bottle with measuring cup is to be packed in printed carton along with pack insert.

6.6 Special Precautions for Disposal and other Handling

No special requirements

## 7. MARKETING AUTHORISATION HOLDER

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## 8. MARKETING AUTHORIZATION NUMBER

Renewal Registration Number: 07408/07816/VAR/2022

## 9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

FIRST AUTHORIZATION: 26/08/2016

## 10. DATE OF REVISION OF THE TEXT

10/07/2023

## 11. REFERENCES