
FlameX Forte Oral Suspension

Composition and Strength of Active Ingredients:

Each 5 ml contains:

Sodium Alginate	250 mg
Dried Aluminium Hydroxide	100 mg
Calcium Carbonate	75 mg
Simethicone	25 mg

Preservative:

Sodium Methyl Paraben	0.14 % w/v
Sodium Propyl Paraben	0.08 % w/v
Cetylpyridinium Chloride	0.10 % w/v

Product Description

Orange colour suspension with peppermint flavour.

Pharmacodynamics

Sodium Alginate is used with an antacid or a H₂ – receptor antagonist, in the management of gastro-oesophageal reflux. The alginate reacts with gastric acid to form a viscous gel (often termed a raft) which floats on top of the gastric contents. This raft then acts as a mechanical barrier to reduce reflux.

Aluminium Hydroxide is an antacid. It is given orally in doses up to 1g, between meals and at bedtime.

Calcium carbonate is used as an antacid, usually in oral doses of up to 1.5g. Calcium carbonate binds phosphate in the gastrointestinal tract to form insoluble complexes and reduce phosphate absorption.

Simethicone reduces the surface tension of gas bubbles, causing them to coalesce. It is used in the treatment of flatulence and meteorism, for elimination of gas, air or foam from the gastrointestinal tract prior to radiography, and for the relief of abdominal distension and dyspepsia. It is often used in conjunction with antacids such as aluminium hydroxide.

Pharmacokinetics

Aluminium hydroxide slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed.

The aluminium compounds remaining in the gastrointestinal tract, which account for most of a dose, form insoluble, poorly absorbed aluminium salts in the intestines including hydroxides, carbonates, phosphates and fatty acid derivatives, which are excreted in the faeces.

Calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestines and the unabsorbed portion is excreted in the faeces.

Simethicone and alginic acid have nil/negligible systemic absorption and act topically.

Indications

FlameX Forte is indicated in the relief of symptoms of gastroesophageal reflux such as acid regurgitation, heartburn and indigestion. It also helps to relieve gastrointestinal conditions caused by excessive gas (flatulence).

Recommended Dose

Adults and children over 12 years: 10-20 ml after meals and at bedtime, up to four times a day.
Children under 12 years: Should be given only on medical advice.

Route of Administration

Oral.

Contraindications

Hypersensitivity to any of the ingredients.

Warning and Precautions

If symptoms do not improve after seven days, the clinical situation should be reviewed.
Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Interactions with Other Medicaments

Aluminium compounds used as antacids interact with many other drugs, both by alterations in gastric pH and emptying, and by direct adsorption and formation of complexes that are not absorbed. Interactions can be minimized by giving the aluminium compound and any other medication 2 to 3 hours apart.

Calcium salts interact with many other drugs, both by alterations in gastric pH and emptying, and by formation of complexes that are not absorbed. Interactions can be minimized by giving calcium carbonate and any other medication 2 to 3 hours apart.

Pregnancy & Lactation

FlameX Forte may be used during pregnancy, but under supervision of a doctor.

Side Effects

Aluminium hydroxide is astringent and may cause constipation; large doses can cause intestinal obstruction.

Excessive doses, or even normal doses in patients with low-phosphate diets, may lead to phosphate depletion accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia.

Calcium carbonate may occasionally cause constipation.

Symptoms and Treatment of Overdose

High doses or prolonged use may lead to gastric hyper secretion and acid rebound. Calcium carbonate can cause hypercalcaemia, particularly in patients with renal impairment or after high doses.

In the event of over dose, Symptomatic treatment should be given.

Storage Condition

Store below 30°C.

Presentation:

100ml and 200ml translucent HDPE bottle with white HDPE cap and a measuring cup.

100ml Amber PET bottle with white HDPE cap and a measuring cup.

Registration Number:

MAL19096033X

Manufactured by & Product Registration Holder:

KCK Pharmaceutical Industries Sdn. Bhd.

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