

STOPACID[®]

Aluminium Hydroxide & Magnesium Trisilicate Suspension/Tablets

Composition

Each 5 ml contains Aluminium Hydroxide BP 120 mg and Magnesium Trisilicate BP 250 mg.

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Pharmacodynamics

Magnesium trisilicate is a hydrated magnesium silicate. It is an antacid with general properties similar to those of Magnesium trisilicate. The laxative effects of Magnesium trisilicate are counteracted by aluminium hydroxide. When magnesium trisilicate is given by mouth, it reacts relatively rapidly with hydrochloric acid in the stomach. About 30% of the magnesium ions are absorbed from the small intestine. The fraction of magnesium absorbed increases if magnesium intake decreases. In plasma, about 25 to 30% of magnesium is protein bound. Oral magnesium salts' doses are eliminated in the urine (absorbed fraction) and the faeces (unabsorbed fraction). Small amounts are distributed into breast milk. Magnesium crosses the placenta. Aluminium hydroxide, given by mouth, slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of aluminium hydroxide to react and may increase the amount of aluminium chloride formed. About 100 to 500 micrograms of the cation is reported to be absorbed from standard daily doses of an aluminium-containing antacid, leading to about a doubling of usual aluminium concentrations in the plasma of patients with normal renal function. Absorbed aluminium is eliminated in the urine, and patients with renal failure are therefore at particular risk of accumulation (especially in bone and the CNS), and aluminium toxicity. 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.

Interactions

Aluminium and magnesium 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 these compounds and any other medication 2 to 3 hours apart. The absorption of aluminium from the gastrointestinal tract may be enhanced if aluminium compounds are taken with citrates or ascorbic acid.

Adverse Effects and Precautions

Aluminium hydroxide, like other aluminium compounds, 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 hypercalcaemia with the risk of osteomalacia. Aluminium salts are not, in general, well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, care is necessary in patients with chronic renal impairment: osteomalacia or adynamic bone disease, encephalopathy, dementia, and microcytic hypochromic anaemia have been associated with aluminium accumulation in such patients given large doses of aluminium hydroxide as a phosphate-binding agent. Similar adverse effects have also been associated with the aluminium content of dialysis fluids.

Aluminium hydroxide used as an adjuvant in adsorbed vaccines has been associated with the formation of granulomas.

Magnesium trisilicate may cause diarrhoea, an effect that is dose-dependent. Hypermagnesaemia may occur, usually in patients with renal impairment. Ingestion of magnesium salts may cause gastrointestinal irritation and watery diarrhoea. There are isolated reports of paralytic ileus in patients receiving magnesium salts. Oral magnesium salts should be used cautiously in patients with renal impairment. Taking with food may decrease the incidence of diarrhoea. Chronic diarrhoea from long-term use may result in electrolyte imbalance.

Oral citrate salts increase the absorption of aluminium from the gastrointestinal tract and patients with renal failure taking aluminium compounds should avoid citrate-containing preparations, which include many effervescent or dispersible tablets.

Indications, Administration and Dosage

Aluminium hydroxide is used as an antacid. It is given in doses of up to about 1 g by mouth, between meals and at bedtime. In order to reduce the constipating effects, aluminium hydroxide is often given with a magnesium-containing antacid, such as magnesium oxide or Magnesium trisilicate/trisilicate. Aluminium hydroxide binds phosphate in the gastrointestinal tract to form insoluble complexes and reduces phosphate absorption. It may thus be used to treat hyperphosphataemia in patients with chronic renal failure (although aluminium accumulation may be a problem), or associated secondary hyperparathyroidism. With this use the dose must be adjusted to the individual patient's requirement but up to about 10 g daily by mouth may be given in divided doses with meals.

Aluminium hydroxide is also used as an adjuvant in adsorbed vaccines. Magnesium trisilicate is an antacid that is given in doses of up to about 1 g by mouth. It is often given with aluminium-containing antacids such as aluminium hydroxide which counteract its laxative effect. Magnesium trisilicate is also given as an osmotic laxative in doses of about 2 to 5 g by mouth. Magnesium trisilicate has also been used as a food additive and as a magnesium supplement in deficiency states. The usual dose for this preparation is 5 to 20 ml taken at meal time, between meals or as needed.

Presentation

Amber bottles containing 100ml suspension.

Blister packs of 10 X 10's tablets and 1000 tablets in Plastic Jars.

Storage

Store in a dry place, below 30°C. Protected from light.

Keep out of reach of children.

Manufactured in Kenya by:



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