

Core Safety Profile

Active substance: Almagate
Pharmaceutical form(s)/strength: Chewable tablets, 500 mg
Oral suspension, 1500 mg and 133 mg
Soft tablet, 1000 mg
P-RMS: ES/H/PSUR/0007/001
Date of FAR: 01.03.2010

4.3. Contraindications

- Hypersensitivity to any of the product components.
- Patients with Alzheimer's disease.
- The existence of undiagnosed gastrointestinal or rectal bleeding, haemorrhoids, oedema, toxæmia of pregnancy and diarrhoea.

4.4. Warnings and special precautions for use

Renal failure

It should be used with caution in patients with severe renal failure because of the possible long-term accumulation of aluminium and magnesium ions in the body.

It should be used with caution in patients on a low phosphorus diet or who have diarrhoea, malabsorption or are severely debilitated, as aluminium salts tend to form insoluble phosphates in the intestine; consequently, absorption is reduced and it is excreted in faeces. In such patients, and above all during prolonged treatment, it may cause hypophosphataemia (anorexia, muscle weakness, general discomfort, etc.) and osteomalacia.

The patient's physician should be informed about the appearance of any symptom indicating bleeding, such as haematemesis or melena.

Use in children

The administration of antacids to children under the age of 12 is not recommended, as these could mask pre-existing illnesses (such as appendicitis). In very small children, there is a risk of hypermagnesaemia or aluminium toxicity, particularly if they are dehydrated or have renal failure.

Use in elderly people

In these patients, the prolonged use of antacids containing aluminium may worsen an existing bone pathology (osteoporosis and osteomalacia) due to the reduction in phosphorus and calcium. Antacids containing aluminium should not be administered to patients with Alzheimer's disease. Research has shown that aluminium may contribute to the development of the illness, as it has been demonstrated that it concentrates in the bundle of nerve fibres in the brain tissue.

Warnings about excipients

Almagate oral suspension in bottles contains 0.525g of sorbitol as an excipient per 7.5ml spoonful. Patients with hereditary fructose intolerance should not take this drug.

Almagate oral suspension in sachets contains 1.05g of sorbitol as an excipient per sachet. Patients with hereditary fructose intolerance should not take this drug.

Almagate 1g soft tablets contain glycerol as an excipient, and may cause headaches, stomach upsets and diarrhoea.

4.5. Interaction with other drugs and other forms of interaction

Because of the potential of antacids to alter the absorption of numerous drugs, they should generally be taken separately.

Studies with non-steroidal anti-inflammatory drugs (flufenamic or mefenamic acid, indomethacin), antiulcer drugs (cimetidine, famotidine, ranitidine), digitalis drugs (digoxin, digitoxin), chlorpromazine, lansoprazole and prednisone have shown a reduction in absorption.

A possible reduction in absorption has been noted with gabapentin and ketoconazole due to variations in gastrointestinal pH.

With drugs such as penicillamine, quinolone (ciprofloxacin), tetracycline (chlortetracycline, demeclocycline, doxycycline) and iron salts (iron sulphate), the decrease in absorption occurs as a result of the formation of insoluble complexes, which is why patients are advised to take the drugs two to three hours apart.

With quinidine, a possible increase in toxicity has been noted as a result of a decrease in its excretion due to urine alkalinisation.

With salicylates (acetylsalicylic acid), studies have demonstrated a reduction in salicylate levels as a result of increased excretion due to urine alkalinisation, particularly with high salicylate doses. Given the probable reduced effect, antacids containing aluminium salt only should be used.

Almagate chewable tablets, almagate oral suspension in a bottle and almagate soft tablets should be taken at least two hours after the administration of any other drug. almagate oral suspension in sachets should be taken at least three hours after the administration of any other drug.

4.6. Pregnancy and breastfeeding

Pregnancy

Some studies have demonstrated isolated cases of hypercalcaemia and hyper- and hypomagnesaemia linked to the chronic consumption of antacids during pregnancy. In addition, there have been isolated cases of increased tendon reflexes in fetuses and newborn babies whose mothers persistently took high doses of antacids containing aluminium or magnesium.

Breastfeeding

Although small amounts of aluminium and magnesium may be excreted in breast milk, the concentration is not high enough to have adverse effects on breastfeeding babies. It may be used during breastfeeding, although patients are advised to avoid chronic and/or excessive use.

4.7. Influence on ability to drive and use machinery

Not applicable.

4.8. Adverse reactions

Almagate is generally well tolerated. Diarrhoea has occasionally been reported. Generally, this is moderate and temporary, and ceases as soon as treatment is suspended.

4.9. Overdose

It may cause hypophosphataemia and osteomalacia as a result of prolonged treatment at high doses or in patients on a low phosphorus diet.