SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ALMAX Oral suspension in bottle
ALMAX FORTE Oral suspension in sachets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

7.5 ml of ALMAX Oral suspension in bottle contain:
Almagate (INN) .....1 g

Each sachet of ALMAX FORTE Oral suspension in sachets contains:
Almagate (INN) .....1.5 g

(For the list of excipients, see 6.1.)

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Gastritis
- Dyspepsia
- Hyperchlorhydria
- Duodenal ulcer
- Gastric ulcer
- Oesophagitis
- Hiatus hernia

4.2. Posology and method of administration

Oral suspension in bottle:
The recommended dose is 1 g (7.5 ml), three times a day, preferably 1/2 - 1 hour after main meals.

Oral suspension in sachets:
The recommended dose is 1.5 g (1 sachet), three times a day, preferably 1/2 - 1 hour after main meals.

In some cases, another dose can be taken before bedtime.
It is not advisable to exceed 8 g/day.

Elderly patients
The posology does not need to be adjusted in this age group (see precautions for use).

Children
Half of the dose applied to adults should be administered from 6 to 12 years of age. The use of the suspension pharmaceutical form is recommended for this age group (see precautions for use).

4.3. Contraindications

Hypersensitivity to any of the components.
Patients with Alzheimer's disease.
Presence of undiagnosed gastrointestinal or rectal haemorrhage, haemorrhoids, oedema, gestational toxaemia, diarrhoea.

4.4. Special warnings and precautions for use

Kidney failure: It should be used with caution in subjects with severe renal impairment due to the possible long-term accumulation of aluminium and magnesium ions in the body.

It should be administered with caution to patients with a low-phosphate diet, diarrhoea, malabsorption or severe weakness, as aluminium salts tend to form insoluble phosphates in the intestines, thereby reducing its absorption and leading to its excretion in faeces. In these patients, particularly with prolonged treatments, it can cause hypophosphatemia (anorexia, muscle weakness, general malaise, etc.) and osteomalacia.

The doctor should be informed of any symptom indicative of haemorrhage, such as hematemesis or melaena.

Use in children: It is not advisable to administer antacids to children under 12 years of age, as they could mask pre-existing conditions (such as appendicitis). In small children, there is a risk of hypermagnesaemia or aluminium toxicity, especially if they are dehydrated or have renal impairment.

Use in the elderly: In these patients, the continued use of antacids containing aluminium can exacerbate existing bone conditions (osteoporosis y osteomalacia), due to a reduction in phosphorus and calcium. Antacids containing aluminium should not be administered to patients with Alzheimer's disease. Research suggests that aluminium may contribute to the disease's development, as it has been shown that it is concentrated in the neurofibrillary tangles found in brain tissue.

Warnings about excipients
ALMAX Oral suspension in bottle contains 0.525 g of sorbitol as an excipient per 7.5 ml. Patients with hereditary fructose intolerance should not take this medication.

ALMAX FORTE Oral suspension in sachets contains 1.05 g of sorbitol as an excipient per sachet.

Patients with hereditary fructose intolerance should not take this medication.

4.5. Interaction with other medicinal products and other forms of interaction

Antacids alter the absorption of several medicinal products so, in general, their administration should be separate from other medicines.

There are studies that show reduced absorption with non-steroidal anti-inflammatory drugs (flufenamic or mefenamic acid, indometacin), ulcer drugs (cimetidine, famotidine, ranitidine), digitalis drugs (digoxin, digitoxin), chlorpromazine, lansoprazole, prednisone.
A possible reduction in absorption due to variations in the gastrointestinal pH has been reported with gabapentin and ketoconazole.

Absorption is reduced with medicinal products such as penicillamine, quinolones (ciprofloxacin), tetracyclines (chlortetracycline, demeclocycline, doxycycline), iron salts (iron sulphate) due to the formation of sparingly soluble compounds, so administration should be 2 or 3 hours apart.

With quinidine, a possible enhancement of its toxicity has been reported, due to reduced excretion caused by urine alkalinisation.

With salicylates (acetylsalicylic acid), some studies show a reduction in salicylate levels, due to greater excretion derived from urine alkalinisation, especially at high doses of salicylate. Antacids with aluminium salt alone should be used, as their effect is probably reduced.

ALMAX Oral suspension in bottle should be taken at least 2 hours after the administration of any other medicinal product. ALMAX FORTE Oral suspension in sachets should be administered at least 3 hours after the administration of any other medicinal product.

4.6. Pregnancy and lactation

Pregnancy: Some studies have detected isolated cases of hypercalcaemia and hyper and hypomagnesaemia associated with the long-term consumption of antacids during pregnancy. Isolated cases have also been described of increased tendon reflexes in foetuses and newborns whose mothers chronically used antacids containing aluminium or magnesium at high doses.

Breast-feeding: Although small amounts of aluminium and magnesium can be excreted in human milk, the concentration is not high enough to cause undesirable effects in the infant. Accepted use, long-term and/or excessive use should be avoided.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8. Undesirable effects

Due to its limited intestinal absorption, adverse reactions to almagate are uncommon.

Gastrointestinal disorders:
Diarrhoea, frequency not known (cannot be estimated from the available data). It is generally mild and transient and disappears when the treatment is discontinued.

4.9. Overdose

Prolonged treatments with high doses or in patients with low-phosphate diets can induce hypophosphatemia and cause osteomalacia

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Therapeutic drug group: ANTACIDS: combination and complexes of aluminium, calcium and magnesium compounds.
ATC code: A02A D03

ALMAX (almagate) is a drug that neutralises hydrochloric acid and inhibits active pepsin. It also absorbs and neutralises biliary acids.

The oral administration of ALMAX neutralises hydrochloric acid. According to the USP (*United States Pharmacopoeia*) method, 1 g of almagate neutralises 28 mmol of HCl.

Various “in vitro” assays have shown a high acid neutralisation rate and the ability to maintain the gastric pH between 3 and 5 for a prolonged period of time without causing over-alkalinisation or a rebound effect.

By aspirating gastric juice from healthy volunteers, it has been shown that almagate is capable of neutralising gastric hydrochloric acid under baseline conditions and after stimulation with pentagastrin, as well as being capable of inactivating pepsin.

In a study with healthy volunteers, there was no significant increase of serum aluminium and magnesium levels after the repeated administration of almagate.
Due to its formulation, this medicinal product has low sodium content.
It does not contain sucrose.

5.2. Pharmacokinetic properties

There is very little intestinal absorption of aluminium and magnesium ions. It occurs only with regard to formed soluble compounds, the excess of which did not precipitate in the intestine.
The limited amount that is absorbed is rapidly excreted through the kidneys, so there is no danger of intoxication when antacids are administered, other than in cases of advanced renal failure or Alzheimer's disease.

5.3. Preclinical safety data

The product is well tolerated at the described doses and under the described conditions.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

ALMAX Oral suspension in bottle:
Purified water
70% non-crystallisable sorbitol
Microcrystalline cellulose
Carmellose sodium
Calcium saccharin
Mint essence
Chlorhexidine acetate
Dimethylpolysiloxane

ALMAX FORTE Oral suspension in sachets:
Purified water
Sorbitol
Microcrystalline cellulose
Carmellose sodium
Calcium saccharin
Mint essence
Chlorhexidine acetate
Simeticone

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

ALMAX Oral suspension in bottle: 5 years.
ALMAX FORTE Oral suspension in sachets: 5 years.

These medicinal products should not be administered after the shelf life stated on the container.

6.4. Special precautions for storage

ALMAX Oral suspension in bottle: Store below 30ºC.
ALMAX FORTE Oral suspension in sachets: Store below 30ºC.

6.5. Nature and contents of container

ALMAX Oral suspension in bottle: glass container, with 225 ml of suspension.

ALMAX Forte Oral suspension in sachets: container with 30 paper/aluminium/polyethylene complex sachets.

6.6. Instructions for use/handling

The suspension bottle should be vigorously shaken before removing the dose using the measuring device provided.

7. MARKETING AUTHORISATION HOLDER

ALMIRALL, S.A.
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8. DATE OF REVISION OF THE TEXT

August 2010

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