PACKAGE LEAFLET
ALMAGEL A

ATC code: AO2A B O2

PHARMACOTHERAPEUTIC GROUP
Antacid agents. Drugs for treatment of peptic ulcer and meteorism. Aluminium compounds.

COMPOSITION
Aluminium hydroxide gel 300 mg, Magnesium hydroxide gel 100 mg, Benzocaine 100 mg, Sorbitol 800 mg in 5 ml suspension.

ACTION
Almagel A is a preparation with an antacid and local anaesthetic effect in the form of a balanced gel of aluminium and magnesium hydroxides. Aluminium hydroxide neutralizes the enhanced secretion of hydrochloric acid in the stomach, forming aluminium chloride. Under the effect of the alkaline intestinal content the latter is transformed into alkaline aluminium salts which are absorbed with difficulty and in practice do not change the concentration of aluminium ions in the blood. Aluminium hydroxide reduces the serum levels of the phosphates by binding phosphate ions in the intestines. Magnesium hydroxide also neutralizes the hydrochloric acid in the stomach, and is transformed into magnesium chloride which has a mild laxative action. The aluminium-containing antacid preparations possess a certain cytoprotective effect on stomach mucosis. Magnesium hydroxide exerts some antiurolithic action. The two components reduce the acidity in the oesophagus too, inducing an increase in pH and a decrease in pepsin activity.
Benzocaine has a local analgesic action in the presence of a pronounced pain syndrome.
Sorbitol exerts a mild flatulence and cholagogue elimination action and a laxative effect as well.
Almagel A does not induce alkalosis and does not form CO$_2$ in the stomach.
Aluminium salts are absorbed in a negligible degree in the intestines.
Magnesium ions are absorbed approximately 10% and almost do not change the concentration of magnesium ions in the blood. The duration of almagel action depends on the time for elimination of food from the stomach. In ingestion on empty stomach the action lasts 20-60 min, and up to 3 hours in intake 1 hours after meals.
Benzocaine is absorbed in small proportions and in practice does not exert any systemic effects. Its local anaesthetic action begins 1-2 min after ingestion.

**INDICATIONS**
Ulcer disease of the stomach and duodenum, acute and chronic hyperacidity, gastritis, secondary colitis, meteorism, oesophagitis, hiatus hernia, pyrosis (also during pregnancy). Gastric hypersecretion; Zollinger-Ellison syndrome; multiple endocrine adenoma; refluxus-oesophagitis; hyperphosphatemia (not recommended in patients with renal insufficiency due to aluminium’s nephrotoxicity); prophylactically during long-term treatment with ulcerogenic agents damaging the gastric mucosis (corticosteroids, reserpine, nonsteroidal anti-inflammatory preparations, alcohol, etc).

**CONTRAINDICATIONS**
Hypersensitivity to any of the components; grave habitual constipation; symptoms of acute appendicitis; metabolic alkalosis; hepatic cirrhosis; severe congestive cardiac insufficiency; pregnancy toxicosis; ulcerous colitis; diverticulosis, colostomy or ileostomy (the risk of hydro- and electrolyte
disbalance is increased); chronic diarrhoea; haemorrhoids (because of the risk of aggravation); intolerance to aluminium- and magnesium-containing medications; renal insufficiency (due to the risk of hypermagnesiemia and aluminium intoxication); allergy to anaesthetics. Though the role of aluminium in the progress of Alzheimer’s disease is not clear (aluminium is accumulated in certain neural structures), the administration of aluminium-containing drugs in this case is not recommended.

ADVERSE REACTIONS/SIDE EFFECTS
Almagel A is well tolerated. Occasionally constipation may occur. In single cases nausea, vomiting, gastric spasms, altered taste in the mouth; hypermagnesiemia, local and systemic allergic reactions have been reported. Long-term administration in patients with renal insufficiency undergoing dialysis treatment may cause neurotoxicity (changes in the mood and mental activity).

DRUG AND NON-DRUG INTERACTIONS
Almagel A changes the acidity (pH) in the stomach which may affect the rate of absorption, bioavailability, maximum plasma concentration and excretion of a large number of simultaneously administered medications. The drug reduces the absorption of H₂-blockers, digitalis glycosides, iron salts, lithium-containing preparations, quinidine, mexiletine, phenothiazines, tetracyclins, ciprofloxacin, isoniazide and ketoconazole. The decreased absorption of these agents is associated with the formation of insoluble complexes and/or the elevated values of pH (alkalisation) in the stomach. In concomitant administration with enterosolvent preparations the increased alkaline pH in the stomach can lead to a more rapid destruction of the enterosolvent coating, which may cause irritation of the stomach and duodenum.
PRECAUTIONS AND WARNINGS

Alcohol and acid-containing foodstuffs such as lemon juice, vinegar etc. should be avoided during treatment with almagel A due to the possibility of weakening the action of the drug.
The medication should not be administered to children because of the risk of development of methaemoglobinaemia.
Almagel A should not be used in combination with sulphonamides since their action is antagonized.
Preferably, other drugs should be taken 1-2 hours before or after almagel A ingestion.
The preparation contains sorbitol which permits its administration in diabetic patients as well.
Usage longer than 3 days is not recommended due to the presence of benzocaine in the medication.
Prolonged treatment in elderly patients may give rise to aggravation of osteo-articular diseases, and possibly of Alzheimer’s disease as well.
Almagel A may change the values of some laboratory and functional studies and tests: it reduces the level of gastric secretion during gastric acidity tests; disrupts the test for imaging of diverticuli with $^{99}$Tc and low-quality bone scintigraphy with $^{99}$Tc, raises the serum levels of gastrin and phosphor; elevates the serum and urinary pH.

PREGNANCY AND BREAST-FEEDING

Repeated administration or usage longer than 3 days during pregnancy is not recommended. The drug should be avoided during the period of breast-feeding.
EFFECTS ON ACTIVE ATTENTION, DRIVING ABILITY AND OPERATION OF MACHINERY

Adverse effects on active attention, reflexes and motor activity have not been reported.

MODE OF ADMINISTRATION AND DOSAGE

Almagel A should be administered only in the presence of pain in the gastrointestinal tract but no longer than 3 days. In adults 1-2 measuring spoonfuls 1-2 hours after meals and in the evening at bedtime. If necessary the single dose can be increased to 3 measuring spoonfuls.

After the pain has passed treatment continues with almagel which does not contain benzocaine.

It is advisable that almagel A is taken undiluted with a little water without taking other liquids for at least 30 min after ingestion.

OVERDOSAGE

In case of single exceeding of the dose no other symptoms except variously manifested constipation have been observed.

Long-term usage of high doses may cause nephrolithiasis, grave constipation, gastric pains, slight sleepiness, hypermagnesiemia. Signs of metabolic alkalosis may also appear: changes in the mood or mental activity, muscle numbness or pain, nervousness and exertional tiredness, slow breathing, unpleasant taste in the mouth. Treatment is symptomatic.

In case of overdosage in children under 10 immediate elimination measures such as gastric lavage, inducing of vomiting, administration of activated charcoal should be taken. The blood count should be monitored due to the risk of developing of methaemoglobinaemia.
DOSAGE FORM AND PACKAGES
Suspension of 170 and 200 ml in 1 bottle and a measuring spoon of 5 ml.

STORAGE
In a dry place protected from light at 15-25°C.