PACKAGE LEAFLET

ALMALOX

COMPOSITION

In 170 ml suspension:

- Aluminium hydroxide 340 mg
- Magnesium hydroxide 395 mg
- Simethicone 36 mg

ACTION

ALMALOX is a drug with soft and prolonged antacid action. It is a balanced gel containing aluminium and magnesium hydroxide in combination with the antiflatulent agent simethicone. Its action is determined by antacid, adsorbtion, detergent and citoprotective properties of the active substances including in its composition.

Almalox has a rapid effect, neutralizes the increased hydrochloric acid and pepsin secretion in the stomach, helps the recovery process by its favourable effect on the protective mechanism of gastro-duodenal mucosa.

Aluminium ion, containing in the preparation increases the tonus of the lower oesophageal sphincter, adsorbs pepsin, bile acids and lysolecitine. This explains its effectiveness in the treatment and prophylaxis of the reflux pathology.

The alkaline components in the preparation are finely dispersed, which increases their active surface, a better contact with gastric and duodenal mucosa is
realized, the evacuation of the stomach content is retarded, which prolongs the neutralisation effect.

The included in its composition simethicone provokes a narrow release and resorption of gas through the intestine walls. It is eliminated from the organism unchanged.

INDICATIONS

Gastrointestinal disorders, manifested with hyper- or normoacidity and increased gas production in the intestines. May be administered as monotherapy or in combination for the treatment of:

- gastritis and gastroduodenitis
- gastric and duodenal ulcer
- gastric and duodenal erosions
- peptic ulcer
- medicamentous gastritis and duodenitis
- reflux oesophagitis
- gastro-oesophageal reflux
- gastro-duodenal reflux
- non-ulcer dyspepsia
- meteorism

The pharmaceutical rapidly relieves pain, acidity, heartburn, heaviness and tension, provoked by the decreased gas production in intestines.

CONTRAINDICATIONS

- In patients with severe renal insufficiency, because of the risk of increase of magnesium and aluminium serum concentrations, due to the decreased excretion through the kidneys;
• Do not use in patients allergic to magnesium and aluminium!

ADVERSE REACTIONS

A progressive aluminium and/or magnesium intoxication is possible to develop in patients with renal insufficiency.

In rare cases diarrhoea can be observed.

DRUG INTERACTIONS

• **Almalox decreases**: maximum plasma concentration and relative bioavailability of captopryl (it should be administered at least 2 hours before the antacid); the resorption of tetracycline, H₂ - blockers and iron, so it is recommended the interval between the almalox intake and tetracycline (resp. H₂ - blockers) administration to be not less than 1-2 hours; plasma concentration of ketoconasol - Almalox should not be administered simultaneously with quinolons.

• **Almalox** should be administered 2 hours before or after digoxin or propranolol intake, because it decreases their bioavailability.

• Depending on patient's renal function the drug can disturb the excretion of quinidine, as quinidine toxicity is revealed.

• **Almalox** administered simultaneously with salicylates causes a significant decrease of salicylate serum level.

• At simultaneous administration of Almalox and levothyroxine reduction of the hormonal effect is observed.

• Pyrepsipine increases and prolongs the effect of Almalox.
SPECIAL PRECAUTIONS FOR USE

Nevertheless the drug is very well tolerated, it is necessary to take into consideration the following:

- Do not take more than 12 teaspoonfuls of the suspension and do not use the maximal dose more than 4 weeks;
- Use cautiously in patients with reduced renal function, because of the risk of hypermagnesemia and/or aluminium intoxication;
- Prolonged administration of the preparation is not recommended in patients with Alzheimer's disease it is thinking that aluminium is concentrated in nerve fibrils of brain tissue and may lead to any complications.

PREGNANCY AND BREAST-FEEDING

- The drug may cause damages in pregnant women because of ethanol (0.113 g in a dose) content in its composition.

- Because of lack of enough clinical experience, Almalox can be used during pregnancy and breast-feeding period only after consult Your physician.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES

No data about the effect on ability to drive and use machines, required high attention have been reported.

SPECIAL WARNINGS

- Each single dose of the drug contains: 0.113 g of ethanol, that may cause damages in patients with liver and brain diseases, with epilepsy and alcoholism; pregnant women and children up to 14 years old; 0.475 g of sorbitol, that is unsuitable in case of hereditary fructose intolerance and can causes gastrointestinal disorders (diarrhoea).
• In case of prolonged treatment (above 45 days) with maximal doses there is a risk of reducing of phosphates and calcium levels in the blood.

ADMINISTRATION AND DOSAGE

PERORALLY!

Intended for use in patients over 14 years of age:

• For a rapid relieving of pain, reducing the heartburn, heaviness in stomach and for the treatment of reflux oesophagitis - 3 teaspoonfuls 4 times daily 1 hour after meal and at bed-time in the evening. Maintenance dose - 2 teaspoonfuls 4 times daily;

• For the treatment of gastritis and gastro-duodenitis, gastric and duodenal ulcer, gastric and duodenal erosion, peptic ulcer, medicamentous gastritis and duodenitis, gastrooesophageal and gastroduodenal refluxes, non-ulcer dyspepsia and meteorism use 2 teaspoonfuls 4 times daily 1 hour after meals and in the evening at bed-time for 30 to 45 days;

• If it is necessary the duration of treatment may be more than 45 days but only by a physician's control.

Almalox is recommended to use undiluted. It is not recommended to intake liquid half an hour after the suspension was applied.

Shake the suspension vigorously before use!

STORAGE

In a dry and protected from direct sunlight place at a temperature below 25°C.
After the first usage store the pack at the same conditions.

EXPIRY TERM

2 (two) years.

Do not use after the indicated expiry term!

Keep the drug out of reach of children!

MARKETING AUTHORISATION HOLDER

Balkanpharma-Troyan AD
1, Krayrechna St.
5600 Troyan