

PACKAGE LEAFLET: Information for the user

ALUKOL

Tablets – 500 mg

(Aluminium hydroxide)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

In this leaflet:

1. What Alukol is and what it is used for
2. Before you take Alukol
3. How to take Alukol
4. Possible side effects
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6. Further information

1. WHAT ALUKOL IS AND WHAT IT IS USED FOR

Alukol contains the active substance colloidal aluminium hydroxide, which is an antacid that reduces the hyperacidity of gastric fluid and thus avoids stomach contractions caused by hyperacidity. Antacid action begins rapidly and usually lasts about 2 hours. Besides the rapid and long-acting neutralization, Alukol also inhibits the action of pepsin (protease), eliminates the harmful effect of gastric acid, which acts as an aggressive factor of the protective barrier of the mucosa.

It is indicated in:

- the treatment of hyperacidity, gastric and duodenal ulcer, ulcer caused by nonsteroidal anti-inflammatory drugs, esophageal reflux, Zollinger-Ellison syndrome, acute and chronic gastritis with hyperacidity, irritation of the mucous membrane of the stomach caused by alcohol, coffee and tobacco consumption.

It reduces the high level of phosphates in the blood that is important in patients with kidney disease who can not eliminate from the body the amount of iron phosphate taken with the diet.

2. BEFORE YOU TAKE ALUKOL

Do not take Alukol if:

- you are allergic to aluminium hydroxide;
- you are allergic to any of the excipients listed at the end of this leaflet;
- you suffer from porphyria;
- you have low level of phosphates in the blood;
- you have severe renal failure;
- the patient is under 12 years old.

If you think you have any of the above-mentioned conditions, do not take the tablets. Talk first to your doctor and follow the given advices. If you go to any other doctor or dentist, inform him that you are taking Alukol.

Take special care with Alukol

Inform your doctor if:

- you are allergic to other drugs, especially if they are in the same class of drugs with Alukol;
- you are taking other drugs, especially antibiotics (such as tetracycline) because aluminium hydroxide reduces their absorption in the human body;
- you have planned to get pregnant during the time you are using Alukol.

In patients with low-phosphate diet, high doses and sometimes usual doses, may cause removal of phosphates, which is associated with increased absorption and urinary excretion of calcium, which constitutes a risk for osteomalacia.

In patients with chronic renal failure who take relatively high doses of aluminium hydroxide, osteomalacia and dementia may also occur.

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken other drugs, even those without a prescription.

Aluminium hydroxide may reduce the bioavailability of anticholinergics, diazepam, quinolones, diflunisal, digoxin, phenothiazines, glucocorticoids, indomethacin, isoniazid, quinidine, propranolol, iron preparations, tetracycline, fat soluble vitamins and phosphates, so these drugs should never be used together, but after an interval of at least two hours.

Antiacids may reduce levothyroxine absorption.

You may need to use different amounts of this drug or take other drugs. Your doctor or pharmacist will advise you.

Taking Alukol with food and drinks

Alukol is a drug which is recommended to be taken before or during meals.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or if you are planning to get pregnant. Like most of this kind of drugs, Alukol is not advised to be used during pregnancy. The doctor or pharmacist will talk about the risks and benefits of taking it during pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you breastfeed the baby.

Aluminium hydroxide passes into breast milk. Your doctor or pharmacist will discuss on the risks and benefits of taking it if you are breastfeeding or you are planning to do so.

Driving and using machinery

Be careful during driving and using machinery until you see how Alukol affects you, although there are no data that Alukol interferes with the driving ability.

Important information about some of the excipients of Alukol

This drug contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ALUKOL

Please follow the advice of your doctor for the way of administration and dosage of Alukol.

The tablets are taken with food, with a glass of water.

0.5 – 1 g (1 – 2 tablets), 4 times daily (before or during meals, also before bedtime).

However, your doctor may advise you to take another dose depending on the condition and your reaction to the drug.

Your doctor may ask you to take Alukol for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Alukol than you should

If you take more Alukol than you should, or if the children have taken this medicine incorrectly, please contact your doctor, the hospital or call the emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Alukol

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose(s).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of time not. Do not get alarmed from this list of possible side effects. None of them may appear to you.

Inform your doctor if any of the following side effects worries you:

- nausea;
- vomiting;
- constipation.

If you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ALUKOL

Keep away from children.

Do not use Alukol after the expiry date which is stated on the package.

Store below 25°C.

6. FURTHER INFORMATION

What Alukol 500 mg tablets contain:

The active substance is colloidal aluminium hydroxide.

One tablet contains 500 mg colloidal aluminium hydroxide.

The excipients are: lactose monohydrate, gelatin, peppermint oil, sodium starch glycolate, magnesium stearate.

Contents of the pack:

Carton box with 30 tablets.

Marketing authorisation holder (MAH) and manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.