

Package leaflet: Information for the patient

Megalac[®] Almasilate

1 g/10 mL suspension

Active substance: almasilate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Megalac[®] Almasilate is and what it is used for
2. What you need to know before you take Megalac[®] Almasilate
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1. What Megalac[®] Almasilate is and what it is used for

Megalac[®] Almasilate is a medicine that neutralises excess stomach acid (antacid).

Megalac[®] Almasilate is used for the symptomatic treatment of diseases where it is required to neutralise acid in the stomach:

- stomach and duodenal ulcers
- heartburn and stomach problems caused by excess stomach acid

2. What you need to know before you take Megalac[®] Almasilate

Do not take Megalac[®] Almasilate

- if you are allergic to almasilate or any of the other ingredients of this medicine (listed in section 6.),
- if your blood phosphate levels are low (hypophosphataemia).

Children and adolescents under 12 years of age

Megalac[®] Almasilate should not be used in children under 12 years of age since only insufficient experience is available for that age group.

Warnings and precautions

Talk to your doctor or pharmacist before taking Megalac[®] Almasilate.

Persisting and recurrent stomach problems may be a sign of a serious disease such as a stomach or duodenal ulcer. Therefore, treatment with Megalac[®] Almasilate should not last longer than 14 days without a medical examination. If tarry stools, blood in stool or vomiting of blood occur, a doctor must be consulted immediately.

In case of long-term use of Megalac[®] Almasilate, serum aluminium levels must be monitored on a regular basis. A level of 40 µg/L should not be exceeded.

In patients with impaired kidney function taking high doses for a long time, poisoning may occur, e.g. in the form of elevated blood magnesium or aluminium levels.

When a patient on a low phosphate diet takes high doses for a long time, they may experience low levels of phosphate, associated with the risk of a softening of bones (osteomalacia). Patients with impaired kidney function therefore should not take high doses for a long time.

Other medicines and Megalac[®] Almasilate

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines.

Megalac[®] Almasilate decreases the resorption and thus also the efficacy of other medicines. This is particularly important for specific antibiotics (e.g. tetracyclines and quinolone derivatives such as ciprofloxacin, ofloxacin, norfloxacin, trovafloxacin) and medicines increasing the strength of the heart (cardiac glycosides). In addition, decreased resorption was documented for the following medicines: halofantrine (medicine used to treat malaria), phenytoin (medicine used to treat epilepsy), H₂ antagonists modelled on cimetidine, ranitidine (medicine used to treat stomach and intestinal ulcers), beta blockers such as propranolol; sotalol (medicine used to treat high blood pressure). In the case of levodopa (medicine used to treat Parkinson's), however, increased resorption was observed.

Alkalisiation of urine during the therapy may affect the excretion of several medicines. This may for instance result in decreased salicylate levels or elevated quinidine levels.

For that reason, other medicines should be taken 1-2 hours before or after taking Megalac[®] Almasilate.

Megalac[®] Almasilate with food and drink

When taking Megalac[®] Almasilate at the same time as acidic drinks (fruit juice, wine), an undesirable increase in aluminium resorption from the intestines may occur. Effervescent tablets also contain fruit acids that may increase aluminium resorption.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

A careful assessment of the benefit-risk ratio is required before antacids containing aluminium are taken during pregnancy. The medicine should only be taken for a short time during pregnancy in order to prevent that the child experiences negative effects associated with the resorption of aluminium.

Breast-feeding

Aluminium compounds are excreted in mother's milk. A risk to the newborn is not to be expected since only very small amounts are resorbed.

Driving and using machines

No special precautions need to be taken.

Megalac[®] Almasilate contains sorbitol.

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 Megalac[®] Almasilate

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by your doctor, the recommended dose is:

Unless prescribed otherwise, take 10 mL Megalac[®] Almasilate (= 2 teaspoons resp. 1 sachet) 4 times daily.

Shake bottle well before use.

Knead sachet well before use.

Method of administration:

Oral use.

This medicine should be taken undiluted 1-2 hours after meals and before going to bed.

Duration of use:

The duration of treatment depends on the type, severity and course of the disease. If symptoms persist for more than 2 weeks while on treatment, a doctor should be consulted.

Talk to your doctor or pharmacist if you think that the effect of Megalac[®] Almasilate is too strong or too weak.

If you take more Megalac[®] Almasilate than you should

No cases of poisoning with Megalac[®] Almasilate are known or expected.

Overdoses can cause a change in bowel habits such as softer stools and increased frequency of bowel movements.

Therapeutic measures are generally not required.

If you forget to take Megalac[®] Almasilate

Do not take a double dose to make up for a forgotten dose.

If you stop taking Megalac[®] Almasilate

In any case, talk to your doctor before you discontinue treatment with Megalac[®] Almasilate or stop it early on your own initiative, e.g. due to side effects.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The stated frequencies of the side effects are based on the following categories:

Very common: may affect more than 1 in 10 treated
Common: may affect 1 to 10 in 100 treated
Uncommon: may affect 1 to 10 in 1,000 treated
Rare: may affect 1 to 10 in 10,000 treated
Very rare: may affect less than 1 in 10,000 treated
Not known: cannot be estimated from the available data

Possible side effects:

Immune system disorders:

Rare: hypersensitivity reactions.

Gastrointestinal disorders:

Not known: with high doses, gastrointestinal complaints such as mushy stools, constipation, flatulence and bloating may occur.

Renal and urinary disorders:

Very rare: silicate stones in the kidneys or bladder in case of long-term therapy.

In patients with severely impaired kidney function, taking medicines containing magnesium and aluminium such as Megalac[®] Almasilate may cause an elevated level of magnesium in the blood (hypermagnesemia) and elevated serum aluminium levels.

Patients with poor function of the kidneys (renal insufficiency) taking high doses for a long time may experience aluminium deposits, in particular in nerve and bone tissue, and low phosphate levels as well as elevated blood magnesium levels to the point of magnesium poisoning symptoms characterised by central nervous symptoms, muscular weakness, loss of reflexes, tiredness, paralysis symptoms, loss of consciousness and irregular heartbeat.

In case of long-term use, aluminium levels should be monitored on regular basis and not exceed 40 µg/L.

Countermeasures for side effects:

In case of gastrointestinal complaints, the Megalac[®] Almasilate dose should be decreased. In case of other side effects, discontinue taking this medicine and consult a doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Megalac[®] Almasilate

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after "EXP:". The expiry date refers to the last day of that month.

Storage conditions:

Do not expose Megalac[®] Almasilate to frost.

6. Contents of the pack and other information

What Megalac[®] Almasilate contains

The active substance is: almasilate.

10 mL (= 2 teaspoons resp. 1 sachet) contain: 1.0 g almasilate (aluminium magnesium silicate hydrate), equivalent to 0.2 g aluminium oxide and 0.3 g magnesium oxide (equivalent to a neutralisation capacity of at least 11 mval).

The other ingredients are:

hyetellose, povidone 25, sorbitol (Ph. Eur.), propylene glycol, saccharin sodium; purified water; caramel flavouring.

Megalac[®] Almasilate contains the sugar-free sweetener sorbitol: 10 mL are equivalent to 0.025 bread units.

What Megalac[®] Almasilate looks like and contents of the pack

Megalac[®] Almasilate is a brown suspension.

Megalac[®] Almasilate is available in packs with one bottle containing 250 mL suspension (N1), 20 sachets containing 10 mL suspension each (N1), 50 sachets containing 10 mL suspension each (N2).

Marketing Authorisation Holder and Manufacturer

Krewel Meuselbach GmbH
Krewelstr. 2
53783 Eitorf
tel: +49 (0)2243 / 87-0
fax: +49 (0)2243 / 87-175
e-mail: info@krewelmeuselbach.de

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