Megalac® Hydrotalcite Chewable Tablets 500 mg

Active substance: hydrotalcite

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 has 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

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1. WHAT MEGALAC® HYDROTALCITE CHEWABLE TABLETS ARE AND WHAT THEY ARE USED FOR

Megalac® Hydrotalcite Chewable Tablets neutralise excess stomach acid (antacid).

Megalac® Hydrotalcite Chewable Tablets are used to treat symptoms of diseases where it is required to neutralise acid in the stomach:
- heartburn and stomach problems caused by excess stomach acid
- stomach or duodenal ulcers

If a stomach or duodenal ulcer is suspected, the patient should be tested for H. pylori; if the test is positive, a recognised antibiotic combination therapy should be considered, since successful use of such a therapy usually also resolves the ulcer disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MEGALAC® HYDROTALCITE CHEWABLE TABLETS

Do not take Megalac® Hydrotalcite Chewable Tablets:
- if you are allergic to hydrotalcite, mint oil or any of the other ingredients of this medicine (listed in section 6).
In patients with impaired kidney function (creatinine clearance < 30 mL/min), Megalac® Hydrotalcite Chewable Tablets may only be taken if magnesium and aluminium serum levels are monitored on a regular basis. If your blood phosphate levels are low (hypophosphataemia), you may only take Megalac® Hydrotalcite Chewable Tablets after consulting with your doctor.

**Children and adolescents under 12 years of age**
Megalac® Hydrotalcite Chewable Tablets should not be used to treat 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® Hydrotalcite Chewable Tablets.

Persisting and recurrent stomach problems may be a sign of a serious disease such as a stomach or duodenal ulcer. Therefore, treatment with Megalac® Hydrotalcite Chewable Tablets 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® Hydrotalcite Chewable Tablets, 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 magnesium or serum 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® Hydrotalcite Chewable Tablets**

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

Megalac® Hydrotalcite Chewable Tablets affect the resorption and consequently also the efficacy of other medicines.

This is particularly important for specific antibiotics (e.g. tetracyclines and quinolone derivatives such as ciprofloxacin, ofloxacin and norfloxacin) and medicines increasing the strength of the heart (cardiac glycosides).

It should also be considered that the solubility of medicines excreted in the urine such as salicylate or quinidine may be affected.

For that reason, other medicines should be taken 1-2 hours before or after taking Megalac® Hydrotalcite Chewable Tablets.
**Megalac® Hydrotalcite Chewable Tablets with food, drink and alcohol**

When taking Megalac® Hydrotalcite Chewable Tablets 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 hydrotalcite is 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® Hydrotalcite Chewable Tablets contain sorbitol and 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 MEGALAC® HYDROTALCITE CHEWABLE TABLETS**

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

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

Take 1-2 Megalac® Hydrotalcite Chewable Tablets several times per day as required.

The daily dose should not exceed 12 chewable tablets, equivalent to 6000 mg hydrotalcite.

One chewable tablet contains 0.821 g sorbitol (equivalent to 0.205 g fructose). The calorific value is 2.6 kcal/g sorbitol.
NB:
Other medicines should in general be taken one to two hours before or after taking Megalac® Hydrotalcite Chewable Tablets (see section 2. "Other medicines and Megalac® Hydrotalcite Chewable Tablets").

Method of administration:
Oral use.

Take Megalac® Hydrotalcite Chewable Tablets between meals and before going to bed with plenty of liquid (1 glass of water). If you have a sensitive stomach, take the chewable tablets during or after meals.

The chewable tablets should be chewed well and swallowed with some liquid (see section 2. "Other medicines and Megalac® Hydrotalcite Chewable Tablets").

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 this medicine is too strong or too weak.

If you take more Megalac® Hydrotalcite Chewable Tablets than you should

Due to the low resorption of aluminium and magnesium, poisoning with Megalac® Hydrotalcite Chewable Tablets is unlikely.

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® Hydrotalcite Chewable Tablets

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

If you stop taking Megalac® Hydrotalcite Chewable Tablets

In any case, talk to your doctor before you discontinue treatment with Megalac® Hydrotalcite Chewable Tablets 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:

Gastrointestinal disorders:
Very common: soft stools.
Very rare:  diarrhoea.

Renal and urinary disorders:
In patients with severely impaired kidney function, taking medicines containing magnesium and aluminium such as Megalac® Hydrotalcite Chewable Tablets 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.

Countermeasures for side effects:

Talk to your doctor or pharmacist if you suffer from diarrhoea during treatment with Megalac® Hydrotalcite Chewable Tablets. A decrease of the dose usually resolves the complaints.

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® HYDROTALCITE CHEWABLE TABLETS

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 push-through foil after "EXP". The expiry date refers to the last day of that month.
Storage conditions:
Do not store above 25°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Megalac® Hydrotalcite Chewable Tablets contain

The active substance is hydrotalcite.

One chewable tablet contains 500 mg hydrotalcite, equivalent to a neutralisation capacity of at least 13 mval HCl.

The other ingredients are:

Lactose monohydrate, hypromellose, sorbitol (Ph. Eur.), calcium behenate (German pharmacopoeia DAB), peppermint flavouring.

One chewable tablet contains 0.821 g sorbitol (equivalent to 0.205 g fructose), which is equivalent to 0.07 bread units. The calorific value is 2.6 kcal/g sorbitol.

What Megalac® Hydrotalcite Chewable Tablets look like and contents of the pack

Megalac® Hydrotalcite Chewable Tablets are white, round tablets, which are flat on both sides.

Megalac® Hydrotalcite Chewable Tablets are available in packs of 20 chewable tablets (N1) und 50 chewable tablets (N2).

Marketing Authorisation Holder and Manufacturer

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