Chewable tablets 500 mg
Active ingredient: Hydrotalcite

Composition
Pharmaceutically active ingredients: 1 chewable tablet contains 500 mg hydrotalcite, equivalent to a neutralisation capacity of at least 13 mval HCL.
Other ingredients: Mannitol, maize starch, magnesium stearate, saccharin sodium, flavouring agents.

Dosage form and content
Original packs containing 20 (N1), 50 (N2) and 100 (N3) chewable tablets.

Mode of action and therapeutic category
Drug product to neutralise gastric hyperacidity (antacid).

Manufacturer
Bayer AG Leverkusen

Indications
For symptomatic treatment of disorders requiring neutralisation of gastric acidity:
- Gastric and duodenal ulcers
- Heartburn and acid-related gastric disorders.

Contraindications
When must Talcid not be used?
Patient with impaired kidney function (creatinine clearance <30 ml/min) may only take Talcid on condition that they have their magnesium and aluminium serum levels checked at regular intervals. Patients with a reduced concentration of phosphates in the blood (hypophosphataemia) must not take Talcid without first consulting their doctor.

What should you be aware of when pregnant or breast-feeding?
This drug product should only be used on short-term basis during pregnancy to avoid aluminium overloading of the child. Aluminium compounds pass into breast milk. Risks to the newborn child are unlikely as only very small quantities are absorbed. There have been no reports of harmful effects of hydrotalcite during pregnancy or breast-feeding. However, no specific studies have been carried out on children or mothers who had taken hydrotalcite during pregnancy or while breast-feeding.

What precautions should be taken for children?
Talcid should not be used to treat children aged below 12 as inadequate experience is available for this age group.

Precautions and warnings
Persistent, recurrent gastric disorders may be signs of a serious condition, such as gastric or duodenal ulcers. Treatment with Talcid should therefore not be continued for longer than 14 days without medical examination.

Consult a doctor immediately if you pass tarry stools or there is blood in your stools or vomit.

Long-term use of Talcid necessitates regular checks of patient’s aluminium level. A level of 40 µg/l should not be exceeded.

Patients with impaired kidney function and chronic consumption of high doses may develop elevated magnesium levels and elevated serum aluminium levels. Long-term use of high doses and a low-phosphate diet (e.g. poor diet or malnutrition) may cause phosphate depletion with the risk of insufficient uptake of minerals into the organic bone matrix (osteomalacia).

Patients with impaired kidney function should therefore avoid long-term use of high doses.

Interactions with other drugs
What other medicines affect the way that Talcid works or are themselves affected by Talcid?
Please note that this information may also apply to medicines used recently.
The absorption and thus also the efficacy of other substances can be reduced by Talcid.
This is particularly important in the case of certain antibiotics (e.g. tetracyclines and quinolone derivatives such as ciprofloxacin, ofloxacin and norfloxacin) and substances used to boost cardiac output (cardiac glycosides).
Attention should also be paid to the potential influence of Talcid on the solubility of medicines that are excreted in urine, e.g. salicylates or quinidine. Other drug products should therefore always be taken 1-2 hours before or after Talcid.

What foods and drinks should you avoid? Concomitant administration of Talcid and acidic drinks (e.g. fruit juice, wine) causes an undesired increase in the absorption of aluminium from the gut. Effervescent tablets also contain fruit acids that can increase aluminium absorption.

Dosage and administration
The following instructions apply for adolescents aged above 12 and adults, provided that your doctor has not prescribed Talcid otherwise. Please follow the directions carefully as otherwise Talcid cannot work properly.

How much Talcid should you take and how often? Chew 1-2 chewable tablets (equivalent to 500-1000 mg Hydrotalcite) several times daily as required.

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

How and when should you take Talcid? Take Talcid several times daily between meals and before going to sleep.

Other medicines should always be taken 1 to 2 hours before or after Talcid (see “Interactions”).

How long should you take Talcid? The duration of treatment depends on the type, severity and course of the disorder.

If symptoms persist for more than 2 weeks of treatment, consult a doctor.

Incorrect use and overdosage
What should you do if you take too much Talcid (either intentionally or by accident)? Intoxication with Talcid is unlikely due to low absorption of aluminium and magnesium.

Overdoses can lead to changed defecation characteristics such as passing of soft stools and increased frequency of defecation. Therapeutic measures are generally not required in these cases.

What should you if you have taken too little Talcid or have forgotten to take a dose? Do not take more chewable tablets next time; simple continue treatment with the prescribed dose.

What should you do if you interrupt the treatment or stop using Talcid before the end of the course? You should always consult your doctor before deciding to interrupt the course of treatment or stop taking Talcid altogether, for example on account of side effects.

Side effects
What side effects can occur when taking Talcid? High doses can cause mushy stools and more frequent defecation. These signs are however unlikely at the recommended dosage. In patients with severely impaired kidney function, use of drug products containing magnesium and aluminium such as Talcid can cause elevated blood levels of magnesium (hypermagnesiaemia) and elevated serum aluminium levels.

Patients with kidney failure who take high doses on a long-term basis may be subject to aluminium deposits, particularly in the nerve and bony tissue, and may develop phosphate deficiency. Patients with kidney failure who are taking Talcid on a long-term basis should therefore have their aluminium levels monitored at regular intervals.

If you experience side effects that are not mentioned in this information leaflet, please inform your doctor or pharmacist.

What action should be taken if any of these side effects occur? Consult your doctor if you experience diarrhoea following treatment with Talcid. Reducing the dose will generally lead to an improvement in the symptoms.

Information on the shelf-life of the product
The expiry date of this pack is printed on the box and on the tablet strips. Do not use the product after this date.

Date of preparation
December 2000

Keep medicines out of the reach of children.
Supplementary information
The following contains more information on the topic of gastric problems:

What kind of symptoms do gastric (e.g. acid-induced) disorders cause?
The following symptoms may occur:
- heartburn, acid belching
- pressure over the stomach
- pain in the upper abdomen

What causes these symptoms?
They can be triggered by, for example:
- stress
- poor dietary habits
- excessive consumption of nicotine, caffeine and/or alcoholic beverages
- and also by certain medicines

How does talcid work?
Talcid brings rapid improvement and relief from stomach disorders:
- Talcid neutralises gastric acid rapidly
- Talcid provides long-acting binding of pepsin and bile acids that can harm the stomach
- Talcid strengthens factors that protect the stomach’s mucous membrane.

Other presentations
Talcid forte: 20, 50, 100 chewable tablets.
Talcid Suspension: 20, 50 sachets each containing 10 ml suspension
Talcid mint: 20 chewable lozenges