PACKAGE LEAFLET: INFORMATION FOR THE USER

BERLITHION

300 mg Capsule, soft

ALPHA LIPOIC (THIOCTIC ACID)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. WHAT BERLITHION IS AND WHAT IT IS USED FOR

Thioctic acid, the active ingredient of Berlithion 300 capsule is a substance that is formed in the body's own metabolism of the higher forms of life and it affects certain metabolic processes in the body. In addition, thioctic acid has properties which protect nerve cells from reactive products of decomposition (antioxidant).
This medicine is prescribed for the treatment of paresthesia in diabetic nerve damage (polyneuropathy).

2. BEFORE YOU TAKE BERLITHION

Do not take BERLITHION

• If you are allergic (hypersensitive) to thioctic acid, the addition of color amaranth or to any other ingredient of Berlithion 300 capsules.

Note:
Children and adolescents should be excluded from the treatment with capsules Berlithion 300, as there is no data for this age group.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Please note that these remarks also apply to medicines that have been recently used.

There is a possibility that concomitant use of Berlithion 300 capsules can cause a weakened effects of cisplatin (anti-cancer agent).

Thioctic acid, the active ingredient of Berlithion 300 capsules, quickly makes chemical bonds with metals (metal chelator) and, as such, it should not be used simultaneously with metal compounds (eg. Iron supplements, magnesium or dairy products for calcium content), as this may cause a weakened effects of the medicine. If the entire daily dose of Berlithion 300 capsules is taken 30 minutes before breakfast, iron and magnesium supplements can be taken in the afternoon or in the evening.

The effect of antidiabetics (insulin or medicines for diabetes that are taken via mouth) can be enhanced. Therefore, careful monitoring of blood sugar is indicated, especially in the initial phase of therapy with capsules Berlithion 300. In order to avoid symptoms of low blood sugar, in isolated cases, it may be necessary to reduce the dose of insulin or a dose of antidiabetic agents, in accordance with the instructions provided by your doctor.

Taking Berlithion 300 capsules with food and drink
Regular alcohol consumption represents a significant risk factor for the onset and progression of diseases accompanied by nerve damage and thus, it can impede the effectiveness of therapy with capsules Berlithion 300. Therefore, it is always recommended that patients with diabetic nerve damage (polyneuropathy) avoid alcohol consumption as much as possible. This also applies to the intervals in which therapy is not received.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
The general principles of pharmacotherapy require that the medicines during pregnancy and lactation may be used only after careful evaluation of the relationship between benefits and risks.
Pregnant and lactating women can receive treatment with thioctic acid only if it is strictly recommended and if the constant monitoring by a doctor is provided, because there is no data for this group of patients. Special animal studies have not provided any evidence regarding the negative impact on fertility or on early embryonic development.

Breast-feeding
No information on possible thioctic acid secretion into breast milk.

Driving and using machines
No special precautions.

Important information's about some ingredients of Berlithion 300 capsules
This medicine contains sorbitol. If your doctor said that you have intolerance to some sugars, you should inform him/her before taking this medicine.

3. HOW TO TAKE BERLITHION

Always take Berlithion 300 capsules exactly as prescribed in this leaflet.
Check with your doctor or pharmacist if you are unsure.

Unless your doctor has prescribed otherwise, the usual dose is as follows:

- 2 Berlithion 300 capsules (ie 600 mg of alpha lipoic (thioctic) acid) approximately 30 minutes before the first meal.

Method of application:

Berlithion 300 capsules should be swallowed whole with plenty of fluid on an empty stomach. Concomitant intake of food may hinder the passage of thioctic acid to the bloodstream. In patients with extended time of gastric emptying is particularly important to take the medicine half an hour before meal / breakfast.

Duration of therapy

Since diabetic polyneuropathy is a chronic disease, it may be necessary to take Berlithion 300 capsules continually.
Your doctor makes a decision in each individual case.

The basis for the treatment of diabetic polyneuropathy is the optimal control of diabetes.

You need to contact your doctor if you have the impression that the effect of Berlithion 300 capsules is too strong or too weak.

If you take more Berlithion 300 capsules than you should.

The overdose may cause nausea, vomiting and headaches.

In the rare cases there were severe symptoms of poisoning, sometimes life-threatening, such as, for example, general convulsions, acid-base equilibrium with excessive blood acidity (lactic acidosis) and severe disorders of coagulation, when more than 10 g of thioctic acid was taken, especially with simultaneous heavy alcohol consumption.
One can therefore say that whenever the overdose or higher accidental intake of Berlithion 300 capsules is suspected (eg. More than 20 capsules of 300 mg in adults or more than 50 mg / kg body weight in children), it is necessary to immediately go to the hospital and take measures in accordance with the general principles of treatment of accidental poisoning.

If you forget to take Berlithion 300 capsules

Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BERLITHION can cause side effects, although not everybody gets them.
Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10
Common: 1 to 10 treated persons of 100
Uncommon: 1 to 10 treated persons of 1000
Rare: 1 to 10 treated persons of 10000
Very rare: less than 1 treated person of 10000
Not known: frequency cannot be estimated from the available data

Side effects

Nervous system disorders
Very rare:
Change or disturbance of taste.

Disorders of the gastrointestinal system
Very rare:
Gastrointestinal symptoms such as nausea, vomiting, stomach or gastrointestinal tract pain, and diarrhea.

Metabolism and nutrition disorders
Very rare:
Improved glucose utilization may cause reduction of blood glucose levels. There have been problems related to low blood sugar levels such as dizziness, sweating, headache and disturbances in the visual field.

Hypersensitivity reactions
Very rare:
Allergic reactions such as rash, hives (urticaria) and itching.
Color addition amaranth can cause allergic reactions.

Precautions
If you notice that you have any of these side effects, you should no longer take Berlithion® 300 capsules. Tell your doctor so that he/she can decide on the severity of the reaction and possible further measures.

At the first sign of hypersensitivity reactions, the treatment with the medicine should be discontinued and you should immediately inform your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BERLITHION

Keep out of the reach and sight of children.

Do not store above 30 ºC.

Do not use BERLITHION after the expiry date which is stated on the label.

6. FURTHER INFORMATION

What BERLITHION contains
The active substance is thioctic acid.
Each soft capsule contains 300 mg of thioctic acid as an active substance.

The other ingredients are:
Fat, medium-chain triglycerides, gelatin, sorbitol (E420), glycerol, titanium dioxide (E 171), Amaranth (E 123)

What BERLITHION looks like and contents of the pack
Package size: Original package with 30 soft capsules.

Regime of dispensing
The medicine is issued on prescription.

Manufacturer
Manufactuer
Berlin-Chemie AG (Menarini Group)
Glienicker Weg 125
12489 Berlin, Germany

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