

Package Leaflet: Information for the User**Thioctacid[®] 600 HR, Film-coated tablets**

For use in adults

Active substance: Alpha-lipoic acid

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Thioctacid 600 HR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Thioctacid 600 HR is and what it is used for
2. Before you use Thioctacid 600 HR
3. How to use Thioctacid 600 HR
4. Possible side effects
5. How to store Thioctacid 600 HR
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1. WHAT THIOCTACID 600 HR IS AND WHAT IT IS USED FOR

Alpha-lipoic acid, the active substance in Thioctacid 600 HR, is a substance which is formed in the body's metabolism and it has an influence on certain metabolic functions of the body. In addition, alpha-lipoic acid has anti-oxidative properties which protect the nerve cell against reactive decomposition products.

Uses:

Thioctacid 600 HR is used for treatment of symptoms of peripheral (sensomotor) diabetic polyneuropathy.

2. BEFORE YOU TAKE THIOCTACID 600 HR**Do not take Thioctacid 600 HR**

- if you are allergic (hypersensitive) to alpha-lipoic acid or any of the other ingredients of Thioctacid 600 HR.

Take special care with Thioctacid 600 HR:

No special precautionary measures required.

After intake of Thioctacid 600 HR, the urine may smell differently, however, this is not of clinical relevance.

Children:

Children and adolescents must not be treated with Thioctacid 600 HR as there is insufficient experience with this age group.

Taking Thioctacid 600 HR with other medicines:

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without prescription.

Please be aware that the following applies also for medicines used recently.

It cannot be ruled out that concomitant use of Thioctacid 600 HR may neutralize the effect of Cisplatin (an anti-cancer agent).

Alpha-lipoic acid, the active substance in Thioctacid 600 HR, readily chemically reacts with metals (metal chelator) and should therefore not be administered together with metal-containing products (e. g. iron preparations, magnesium preparations and milk products due to their calcium content) because it may neutralize their effect. If you take Thioctacid 600 HR 30 minutes before breakfast, you may take your iron and/or magnesium preparations at lunchtime or in the evening.

The blood-sugar reducing effect of anti-diabetic agents (insulin and/or other anti-diabetic agents) may be enhanced. Therefore - in particular when starting treatment with Thioctacid 600 HR – fine-meshed monitoring of the blood-sugar values will be required. In order to avoid symptoms of hypoglycaemia, it may become necessary in individual cases to reduce the dose of insulin and/or of the oral anti-diabetic agent according to the instructions given by the treating physician.

Taking Thioctacid 600 HR with food and drink

Regular consumption of alcohol is an important risk factor for the development and the progression of neuropathic clinical pictures and may therefore also have a negative influence on the success of treatment with Thioctacid 600 HR. For this reason, it is generally recommended for patients suffering from diabetic neuropathy (polyneuropathy) to avoid the consumption of alcohol as far as possible. This shall also apply to treatment-free intervals.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

It is one of the general principles of drug therapy that any medicinal product shall be used during pregnancy and/or the breast-feeding period only after the risk-benefit ratio has been weighed carefully.

Therefore, it is recommended that pregnant and/or breast-feeding women shall undergo treatment with alpha-lipoic acid only after careful recommendation and monitoring by their doctor as there is no experience with these patient collectives so far. Special animal studies have not shown any indication of fertility disorders or harmful effects on foetal development.

There are no reports about a possible passage of alpha-lipoic acid into the breast milk.

Driving and using machines

No special precautionary measures need to be taken.

3. HOW TO TAKE THIOCTACID 600 HR

Always take Thioctacid 600 HR exactly as specified in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

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

Unless otherwise prescribed, the daily dose is 1 film-coated tablet of Thioctacid 600 HR (equivalent to 600 mg of alpha-lipoic acid), to be taken in form of a single dose about 30 minutes prior to the first meal.

Method of administration:

Take Thioctacid 600 HR Film-coated tablets unchewed and with an appropriate quantity of liquid on an empty stomach. The uptake of food at the same time may impair the passage of alpha-lipoic acid in to the blood circulation. For this reason it is very important – in particular in patients with prolonged gastric emptying time – that the tablet will be taken half an hour before the first meal.

Duration of treatment:

Due to the fact that diabetic neuropathy is a chronic disease it may be that you will have to take Thioctacid 600 HR for your lifetime.

Your doctor will decide in your individual case.

Should you have the impression that the effect of Thioctacid 600 HR is either too strong or too weak, discuss this with your doctor or your pharmacist.

If you take more Thioctacid 600 HR than you should

In case of overdosing, nausea, vomiting and headache may occur.

In isolated cases, severe – partially life-threatening - intoxication symptoms (including generalized seizure, imbalance of the acid-base equilibrium accompanied by acidosis of the blood and/or severe disorders of blood clotting) were seen after intake of more than 10 g of alpha-lipoic acid, in particular in connection with high consumption of alcohol.

For this reason, suspected significant overdosing with Thioctacid 600 HR (e. g. more than 10 tablets containing 600 mg in adults and more than 50 mg/kg of body weight in children) shall require immediate admission to a hospital and initiation of standard measures used to treat intoxication (e. g. induction of vomiting, gastric lavage, activated charcoal, etc.).

Treatment of any occurring symptoms of intoxication shall be based on the principles of modern intensive care and shall be carried out symptomatically.

If you forget to take Thioctacid 600 HR

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

If you stop taking Thioctacid 600 HR

Do not stop taking Thioctacid 600 HR without first consulting your doctor. Otherwise, your symptoms may aggravate.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Thioctacid 600 HR can cause side effects, although not everybody gets them.

Evaluation of the side effects is based on the following frequency information:

Very common:	more than 1 of 10 treated patients
Common:	less than 1 of 10, however more than 1 of 100 treated patients
Uncommon:	less than 1 of 100, however more than 1 of 1,000 treated patients
Rare:	less than 1 of 1,000, however more than 1 of 10,000 treated patients
Very rare:	less than 1 of 10,000 treated patients, including isolated reports

Possible side effects:

Gastro-intestinal tract:

Common:

Vertigo

Very rare:

Vomiting, pain in the stomach and/or in the intestine and diarrhoea.

Hypersensitivity reactions:

Very rare:

Allergic reactions such as skin rash, nettle rash (urticaria) and itching.

Nervous system:

Common:

Dizziness

Very rare:

Change or disturbance of taste sensation

General disorders:

Very rare:

Due to enhanced glucose utilization, the blood-sugar level may drop. In this relation, hypoglycemic symptoms accompanied by dizziness, sweating, headache and blurred vision were described.

Countermeasures:

If you experience any symptoms of the side effects mentioned above, do not take Thioctacid 600 HR again. Please inform your doctor. He/she will then make a decision on the severity as well as on any further measures, if appropriate.

Upon the first symptoms of an allergic reaction, stop taking this medicine and contact a doctor immediately.

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 THIOCTACID 600 HR

Keep out of the reach and sight of children.

Do not use Thioctacid 600 HR after the expiry date which is stated on the carton and the container after "Use before".

Storage conditions

Store the container in the carton to protect the film-coated tablets from light and moisture.

Do not store above 25°C.

6. FURTHER INFORMATION

What Thioctacid 600 HR contains

The active substance is alpha-lipoic acid.

1 film-coated tablet contains 600 mg of alpha-lipoic acid.

The other ingredients are:

Poly(O-2-hydroxypropyl)cellulose (5.0 – 16.0% of hydroxypropoxy groups), Magnesium stearate, Hydroxypropyl cellulose, Hypromellose, Macrogol 6000, Talc, Titanium dioxide (E 171), Quinoline yellow, Aluminium salt (E 104), Indigo carmine, Aluminium salt (E 132)

How Thioctacid 600 HR looks like and contents of the pack

Container:

Amber glass bottle, hydrolytic class III, with originality closure from polyethylene

Thioctacid 600 HR is available in packs containing 30, 60 and 100 film-coated tablets each.

Marketing Authorisation Holder and Manufacturer

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Prescription drug only