

**Package Leaflet: Information for the User****Thioctacid® 600 T**

Solution for Injection contains 600 mg alpha-lipoic acid

For use in adults

Active substance: Alpha-lipoic acid, Trometamol salt (1:1)

**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 T 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 T is and what it is used for
2. Before you use Thioctacid 600 T
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**1. WHAT THIOCTACID 600 T IS AND WHAT IT IS USED FOR**

Alpha-lipoic acid, the active substance in Thioctacid 600 T, is a substance which is formed in the body's metabolism and it has an influence on certain metabolic functions of the body. Moreover, alpha-lipoic acid has anti-oxidative properties which protect the nerve cell against reactive decomposition products.

**Uses:**

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

**2. BEFORE YOU USE THIOCTACID 600 T**

**Do not use Thioctacid 600 T**

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

**Take special care with Thioctacid 600 T:**

In relation with the use of Thioctacid 600 T as solution for injection and/or infusion, allergic reactions (hypersensitivity reactions) up to life-threatening shock (acute collapse of the circulation) were seen (refer to section "Side Effects").

Therefore, your treating physician will monitor you for the occurrence of early symptoms (such as itching, nausea, sickness etc.) while you are treated with Thioctacid 600 T. Should these symptoms occur, treatment must be stopped immediately and further therapeutic measures must be taken, if appropriate.

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

**Children:**

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

**Using Thioctacid 600 T 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 T may neutralize the effect of Cisplatin (an anti-cancer agent).

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 T – 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 T 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 T. 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 USE THIOCTACID 600 T**

Always use Thioctacid 600 T 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:**

In cases of symptoms of peripheral (sensomotor) diabetic polyneuropathy, the daily dosage is one ampoule of Thioctacid 600 T (equivalent to 600 mg of alpha-lipoic acid).

### **Method of administration:**

Thioctacid 600 T can be given either by intravenous injection of the undiluted solution or mixed with physiological salt solution in form of an intravenous drip (short-duration infusion). In these cases, Thioctacid 600 T must be administered over a period of not less than 12 minutes.

Due to the fact that the active substance is sensitive to light, the short-duration infusion shall be prepared just shortly before its use. The infusion solution must be protected from light (e. g. by means of aluminium foil). When protected from light, the infusion solution has a shelf life of about 6 hours.

### **Duration of treatment:**

During the initial phase of treatment, the injection solution will be used for a period of 2 to 4 weeks.

It is recommended to continue treatment by taking 600 mg of alpha-lipoic acid in form of tablets for oral use.

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

### **If you take more Thioctacid 600 T 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 uptake 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 T shall require immediate admission to a hospital and initiation of standard measures used to treat

intoxication. 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 use Thioctacid 600 T**

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

**If you stop using Thioctacid 600 T**

Do not stop treatment with Thioctacid 600 T 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 T can cause side effects, although not everybody gets them.

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

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

Possible side effects:

***Gastro-intestinal tract***

*Uncommon:*

Nausea and vomiting

***Application site reactions***

*Very rare:*

Reactions at the application site

***Hypersensitivity reactions***

Allergic reactions such as skin rash, nettle rash (urticaria) and itching as well as allergic reactions of the whole body up to shock may occur.

***Nervous system:***

*Uncommon:*

Change or disturbance of taste sensation

*Very rare:*

Cramps as well as double vision

***Blood and blood vessels***

*Very rare*

Skin bleeding (purpura), disorders of the blood platelets and consequently of blood clotting (thrombopathy)

***General disorders***

*Common:*

After rapid intravenous injection, pressure in the head and difficulty in breathing may appear which will remit spontaneously.

*Very rare:*

Due to enhanced glucose utilization, the blood-sugar level may drop. In this relation, hypoglycaemic 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 use Thioctacid 600 T 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 you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE THIOCTACID 600 T**

Keep out of the reach and sight of children.

Do not use Thioctacid 600 T 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 content from light.

**Information concerning in-use shelf life**

- Protect an infusion solution prepared with Thioctacid 600 T from light (e. g. by means of aluminium foil).
- When protected from light, the infusion solution prepared with physiologic salt solution has a shelf life of 6 hours.

**6. FURTHER INFORMATION**

**What Thioctacid 600 T contains:**

The active substance is:

24 ml of Solution for Injection contain 952.3 mg of alpha-lipoic acid, Trometamol salt (equivalent to 600 mg of alpha-lipoic acid)

The other ingredients are:

Trometamol, Water for injection

**How Thioctacid 600 T looks like and contents of the pack:**

**Container:**

25-ml amber glass ampoules, hydrolytic class I, with colour ring coding;  
packed in PS blisters containing 5 ampoules each, sealed with PS film, white, 500 µm

**Pack sizes:**

Original pack of 5 ampoules (N1) containing 24 ml of solution for injection each.

Original pack of 10 ampoules (N2) containing 24 ml of solution for injection each.

Original pack of 20 ampoules (N3) containing 24 ml of solution for injection each.

**Marketing Authorization Holder**

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Prescription drug only