

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 more 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.

TIACID 300 mg film-coated tablets **TIACID 600 mg film-coated tablets**

What is in this leaflet?

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2. Before you take **TIACID**
3. How to take use **TIACID**
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1. What TIACID is and what it is used for

Alpha lipoic acid, the active ingredient of **TIACID** mg film-coated tablets 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, Alpha lipoic 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 TIACID **Do not take TIACID**

If you are allergic (hypersensitive) to Alpha lipoic acid, the addition of color amaranth or to any other ingredient of **TIACID** film-coated tablets.

Note: Children and adolescents should be excluded from the treatment with film-coated tablets **TIACID**, 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 **TIACID** film-coated tablets can cause a weakened effects of cisplatin (anti-cancer agent).

Alpha lipoic acid, the active ingredient of **TIACID** film-coated tablets, 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 **TIACID** film-coated tablets 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 film-coated tablets **TIACID**. 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 **TIACID** film-coated tablets 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 film-coated tablets **TIACID**.

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 Alpha lipoic 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 Alpha lipoic acid secretion into breast milk.

Driving and using machines

No special precautions.

Important information's about some ingredients of **TIACID** film-coated tablets

This medicine contains lactose. If your doctor said that you have intolerance to some sugars, you should inform him/her before taking this medicine.

3. How to take TIACID

Always take **TIACID** film-coated tablets 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:

1 **TIACID** film-coated tablet (600 mg of alpha lipoic (thioctic) acid) approximately 30 minutes before the first meal.

Method of application:

TIACID film-coated tablets should be swallowed whole with plenty of fluid on an empty stomach. Concomitant intake of food may hinder the passage of Alpha lipoic 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 **TIACID** film-coated tablets 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 **TIACID** film-coated tablets is too strong or too weak.

If you take more **TIACID** film-coated tablets 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 10g of Alpha lipoic acid was taken, especially with simultaneous heavy alcohol consumption.

One can therefore say that whenever the overdose or higher accidental intake of **TIACID** film-coated tablets is suspected (eg. More than 20 film-coated tablets of 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 TIACID film-coated tablets

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

4. Possible side effects

Like all medicines, **TIACID** 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 **TIACID** film-coated tablets. 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 Tiacid

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

6. Further information

What TIACID contains

The active substance is Alpha lipoic acid.

TIACID 300 mg film-coated tablet:each film-coated tablet

contains 300 mg of alpha lipoic acid as an active substance.

TIACID 600 mg film-coated tablet:each film-coated tablet contains 600 mg of alpha lipoic acid as an active substance.

The other ingredients are: lactose monohydrate, hydroxypropylcellulose, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, colloidal silicon anhydrous, stearic acid, talc, magnesium stearate.

Movie: Opadry II yellow.

What TIACID looks like and contents of the pack

Package size: Original package with 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75300 Lukavac

Bosnia and Herzegovina

Date and number of renewal of marketing authorization

Tiacid, film-coated tablets, 30 x 300 mg:

Number: 04-07.3-2-5862/16 **Date:** 30.03.2017.

Tiacid, film-coated tablets, 30 x 600 mg:

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