

Package leaflet: Information for the patient

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.



TINAZOL film-coated tablets 500 mg *Tinidazole*

What is in this leaflet:

1. What **Tinazol** is and what it is used for
2. What you need to know before you take **Tinazol**
3. How to take **Tinazol**
4. Possible side effects
5. How to store **Tinazol**
6. Contents of the pack and other information

1. What Tinazol is and what it is used for
Tinazol film-coated tablets contain the active substance tinidazole which belongs to a group of drugs-antimicrobics, imidazole derivatives.

Your doctor prescribed **Tinazol** for treatment

- stomach and duodenum ulcer caused by *Helicobacter pylori*, in combination with other medicines,
- anaerobic infections, such as abdominal inflammation, gynecological infections, infections after surgery, skin and soft tissue infections, sepsis,
- infection of the upper and lower parts of the respiratory tract,
- non-specific vaginitis,
- ulcerative gingivitis (inflammation of the dental meat),
- inflammation of the urogenital system caused by the bacterium *Trichomonas vaginalis*,
- Giardiasis (small intestine mucosa infection caused by *Giardia lamblia*, by parasitic protozoan),
- intestinal and liver amebiasis (a disease caused by an *Entamoeba histolytic* parasite).

Tinazol is used in the prevention of infections after surgery.

2. What you need to know before you take Tinazol

Do not take Tinazol if:

- you are allergic (hypersensitive) to tinidazole or any similar drugs or to any of the other ingredients
- you have a blood disorder or a history of blood disorders
- you have central nervous system (CNS) disease, including epilepsy
- you are pregnant or you are breast-feeding
- you have severe liver disease

Warnings and precautions

Inform your doctor about any health problems you have or have had, as well as about all allergies. Tell your doctor if:

- you feel dizzy, disturbances in movement coordination
- inability to maintain balance and/or tension limbs, because your doctor will stop your treatment with tinidazole;

If you use this medicine to treat trichomoniasis (a sexually transmitted disease), the partner should also be treated at the same time.

Other medicines and Tinazol

Tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription.

You should tell your doctor if you are currently taking blood thinners such as warfarin to prevent blood clots as your doctor may wish to monitor you more closely.

Tinazol with food and drink

Alcoholic drinks should be avoided during the use of tinidazole due to the possibility of occurrence similar to a disulfiramic reaction (redness, abdominal cramps, vomiting, rapid heart rate). The use of alcohol should be avoided up to 72 hours after stop of the use of tinidazole.

Children and adolescents

Tinidazole is not used in the treatment of children under 12 years of age due to lack of evidence of safety and efficiency of application.

Pregnancy and breast-feeding

Tinazol should not be used during pregnancy. Always contact your doctor or pharmacist for advice before taking **Tinazol** or any other medicine. Do not take this medicine if you are breast-feeding because small amounts of the medicine can pass into your breast milk. If you stop breastfeeding while using **Tinazol**, you should not start breastfeeding at least 3 days after stopping using **Tinazol**.

Driving and using machines

Do not drive or use machinery if this medicine makes you feel drowsy or gives you problems with co-ordination or sensation (e.g. numbness or weakness).

Important informations about some ingredients in Tinazol

If your doctor has told you that you have a intolerance of some sugars, before you start taking **Tinazol**, consult your doctor. This medicine contains lactose, and you should take care of this if you have diabetes.

3. How to take Tinazol

Your doctor will decide on the appropriate dose of **Tinazol**, depending on your condition and whether you are taking other medicines. Take **Tinazol** for as long as the doctor prescribed. Do not take more tablets than the prescribed dose.

Stomach or duodenum ulcer

The usual dose of tinidazole is 500 mg/2 times a day in combination with two additional medicines recommended by your doctor as part of a triple therapy.

Anaerobic infections

Treatment begins with a dose of 2 g on the first day. Treatment is continued at a dose of 1 g once or divided into two individual doses of 500 mg. Treatment usually lasts 5-6 days, but depending on the clinical assessment it can be extended to more than seven days.

Non-specific vaginitis

Non-specific vaginitis has been successfully treated

with a single oral dose of 2 g. The best results are with 2 g single dose/two consecutive days (total dose 4g).

Acute ulcerative gingivitis

Treatment is performed using a single dose of 2 g.

Inflammation of the urogenital system caused by the bacterium *Trichomonas vaginalis*

Treatment is performed using a single dose of 2 g. It is recommended to treat both partner at the same time.

Children

Treatment is administered with a single dose of 50 to 75 mg/kg of body weight.

Giardiasis

Treatment is performed using a single dose of 2 g.

Children

The dose for children is 50 to 75 mg/kg of body weight, at once.

Gut and liver amebiasis

The daily dose is 1,5-2 grams in a period of 2 to 3 days. In case of incomplete healing, the therapy can be extended up to 6 days.

Children

Treatment is administered with a single dose of 50 to 60 mg/kg of body weight per day. Treatment lasts 3-5 days.

Elderly/Patients with Renal Function

No dose adjustment is required.

Patients with severe hepatic impairment

If you have severe damage to your liver function, you should not take tinidazole.

Children <12 years old

There are no available data on the safety and efficacy of tinidazole for the treatment of this age group, and the medicine in children under 12 years of age is not used.

If you think **Tinazol** film-coated tablets are too weak or too strong for your organism, you should contact your doctor.

If you take more TINAZOL than you should

In case of overdose, contact your doctor immediately so that you can immediately get medical attention. So far there have been no overdoses.

If you forget to take Tinazol

You should take **Tinazol** film-coated tablets as prescribed for you. However, if you forget to take a single dose, take the next as soon as possible, and continue with the treatment as prescribed. If the time for taking the next dose is near, wait and then take the medicine. Never take a double dose to make up for a missed dose.

If you stop taking Tinazol

You should not stop using this medicine without the advice of a doctor, because this can lead to your own incomplete healing.

4. Possible side effects

Like all medicines, this medicine causes side effects, although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips or tongue
- sudden uncontrolled outbursts of intense emotions, laughter, cough, or other actions or activities or attacks.

The common side effects (that may affect up to 1 in 10 people) are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

- nausea (feeling sick) or vomiting, loss of appetite, diarrhoea, stomach pain or cramps
- headache
- vertigo
- skin rash or itching (especially affecting the whole body).

The frequency of the following side effects is not known (cannot be estimated from the available data).

You should contact your doctor if you notice any of the following:

- numbness, tingling, pain or weakness in hands or feet
- clumsiness or unsteadiness
- fever or chills and painful ulcers in the mouth
- sore or swollen mouth/tongue
- redness of the face or neck
- dizziness
- tiredness
- dark urine
- tongue discolouration or unpleasant metallic taste.

Tinazol film-coated tablets can sometimes cause a temporary reduction in white blood cells which does not usually give you any symptoms.

Reporting of side effect

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Tinazol

Keep all medicines out of the sight and reach of children. Store below 30°C in a dry place. Do not take this medicine after the expiry date stamped on the pack after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

Tinazol 500 mg

Each film-coated tablet contains 500 mg of tinidazole as an active substance.

The other ingredients are: lactose monohydrate, pregelatinized starch, povidone, sodium starch glycolate, magnesium stearate.

Film: Opadry II white, purified water

What Tinazol look like and contents of the pack

Box with 4 film-coated tablets of 500 mg tinidazole in blister packs, in a box.

Box with 14 film-coated tablets of 500 mg tinidazole in blister packs, in a box.

Marketing Authorisation Holder and manufacturer

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac, Bosnia and Herzegovina.

This leaflet was last revised in: 12.2016.

Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:

TINAZOL, film-coated tablets, 4x500 mg:

Date: 21.12.2016.

Number: 04-07.3-2-6614/16

TINAZOL, film-coated tablets, 14x500 mg:

Date: 21.12.2016.

Number: 04-07.3-2-6615/16