

PACKAGE LEAFLET: Information for the patient
TINAZOL® 500 mg film-coated tablets
Tinidazole

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. See section 4.

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
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1. WHAT TINAZOL IS AND WHAT IT IS USED FOR

Tinazol contain tinidazole. It is used to fight certain parasites and bacteria

Tinazol is indicated for the oral treatment of :

certain vaginitises, especially those caused by by *Trichomonas vaginalis* or *Gardnerella vaginalis*,

- certain urinary infections in men and women caused by *Trichomonas vaginalis*
- certain digestive parasitic infections caused by *Entamoeba histolytica* (amoeba that can cause intestinal and liver infections) or by *Giardia lamblia* (intestinal infections)
- certain bacterial infections caused by anaerobic microbes; mainly *Bacteroides fragilis*, other species of *Bacteroides* and *Fusobacteria* and also by species of *Peptococcus*, *Peptostreptococcus*, *Clostridia*, *Eubacteria* and *Veillonella*.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TINAZOL

Do not take Tinazol :

- If you are allergic to tinidazole, to a drug with a similar chemical structure (5-nitroimidazol) or to any of the other ingredients listed in section 6:
- If you have or have had a blood disease;
- If you suffer from organic neurological disorders;
- During the first trimester of pregnancy and breastfeeding (see section “Pregnancy and breast-feeding”).

Warnings and precautions

Talk to your doctor, pharmacist before you taking this medication.

- If you experience symptoms such as dizziness, lightheadedness, incoordination, coordination disorders, peripheral nervous system disorder or convulsions: in this case, stop the treatment immediately and consult your doctor.

- The intake of alcoholic beverages should be avoided during treatment and for at least 3 days after stopping treatment with Tinazol because of the risk of side effects (see also section "Tinazol with food, drinks and alcohol"). Do not use Tinazol for longer than prescribed by your doctor..

Strictly follow the indications of your doctor, especially the treatment duration.

Other medicines and Tinazol

Tell your doctor or pharmacist if you are taking, have recently taken, or may take any other medicines. Tinazol, like other drugs with a similar chemical structure, may increase the activity of certain oral anticoagulants (blood thinners drugs such as warfarin, acenocoumarol, dicoumarol, anisindione, phenindione and phenprocoumon). Your doctor will adjust the dose of the anticoagulant if necessary.

Taking Tinazol with food or drink and alcohol

The intake of alcoholic beverages should be avoided during treatment and at least for three days after stopping treatment, as a disulfiram effect (abdominal cramps, vomiting, hot flushes, increased heart rate) may occur.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medication.

Tinazol crosses the placental barrier. This drug is therefore contraindicated during the first trimester of pregnancy. During the second and third trimester, it should only be administered on the advice of your doctor if absolutely necessary.

Breastfeeding is contraindicated during treatment and at least three days after discontinuation of Tinazol treatment, as this drug is excreted in breast milk.

Driving and using machines.

The effect of tinidazole on the ability to drive and operate machinery has not been studied.

However, there is no reason to believe that tinidazole may affect these faculties. This medicine contains sodium methyl and sodium propyl para-hydroxybenzoate which can cause allergic reactions (possibly delayed).

3. HOW TO TAKE TINAZOL ?

Always take this drug exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take your Tinazol tablets with half a glass of water, preferably during or after a meal.

Use in adults

The recommended dose is :

- Urinary (in men and women) or vaginal infection caused by *Trichomonas vaginalis*: 4 tablets in a single dose. The same treatment is recommended for the sexual partner.
- Vaginitis caused by *Gardnerella vaginalis*: 4 tablets per day, during 1 to 2 days.
- Acute intestinal infection caused by *Entamoeba histolytica*: 4 tablets per day, during 2 to 3 days (up to 6 days if needed).
- Liver abscess caused by *Entamoeba histolytica*: 3 to 4 tablets per day during 3 to 6 days.
- Intestinal infection caused by *Giardia lamblia*: 4 tablets in a single dose.
- Anaerobic bacterial infections: 4 tablets on the first day, then 2 tablets per day for the next 4 to 5 days (total: 5 to 6 days of treatment).

The medication will be taken daily in a single dose, within the meal.

Use in children and adolescents

For children over 12 years of age, the recommended dose is :

- Urinary or vaginal infections caused by *Trichomonas vaginalis*: 50 to 75 mg/kg, once (repeat 1 time if necessary)
- Acute intestinal infection caused by *Entamoeba histolytica*: 50-60 mg/kg per day during 3 days
- Hepatic abscess caused by *Entamoeba histolytica*: 50 to 60 mg/kg, during 5 days
- Intestinal infection caused by *Gardia lamblia*: 50 to 75 mg/kg, in 1 time (repeat 1 time if necessary)

Administration to children under 12 years of age is not recommended.

The maximum adult dosage should not be exceeded for a child.

The medication should be taken as a single dose each day within the meal.

Use in patients with hepatic failure

If you have liver failure, caution is recommended, especially if the duration of the treatment is longer than 5 days. Consult your doctor.

Use in the patient with severely decreased kidney function

Dosage adjustment is generally not necessary in patients with impaired renal function. However, because tinidazole is readily eliminated by hemodialysis, patients may require additional doses of Tinazol to compensate for this elimination.

Your doctor will tell you how long you will need to take Tinazol. Do not stop taking Tinazol prematurely as your infection may not be cured. If there is no improvement, please see your doctor again.

If you take more Tinazol than you should:

If you have taken too much Tinazol, contact your doctor, pharmacist or Anti-poison center immediately. If too high doses are used (= overdose), symptomatic and supportive treatment will be instituted. Gastric lavage may be helpful. Tinidazole is easily dialyzable.

If you forget to take Tinazol

Do not take a double dose to make up for the forgotten dose. Take the next dose according to the usual schedule.

If you stop taking Tinazol

Do not stop your treatment prematurely as symptoms may reappear if all bacteria and parasites are not killed.

Always check with your doctor if you plan to stop the treatment.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines Tinazol may cause side effects, although not everybody gets them.

In rare cases, this medicine can cause a serious and potentially fatal allergic reaction (anaphylactic shock). If you experience rapid onset of difficulty breathing, swelling of the face and throat, or general malaise (shock), contact a doctor immediately.

Common side effects (may affect up to 1 in 10 patients)

- Decreased appetite
- Headaches
- Vertigo
- Vomiting, diarrhoea, nausea, abdominal pain
- Inflammation of the skin of allergic origin, itching.

Very rare adverse events (may affect up to 1 in 10,000 patients)

- Severe skin reactions (such as erythema multiforme, Stevens-Johnson syndrome, epidermal necrolysis)

Adverse events of undetermined frequency (cannot be estimated based on available data)

- Decrease in the number of white blood cells (leukopenia)
- Severe allergic-type reactions, drug allergies
- Convulsions, peripheral nervous system disorder, tingling (paresthesia), sensitivity deficit (hypoesthesia), sensory disturbances, coordination disorder (ataxia), dizziness, taste alteration (dysgeusia)
- Hot flashes
- Inflammation of the tongue, inflammation of the mouth, discolouration of the tongue
- Angioedema, urticaria
- Excessive staining of the urine (chromaturia)
- Fever, fatigue
- Blood tests: modifications of clinical biology tests

During treatment with Tinazol, you may develop an additional vaginal infection due to *Candida albicans*.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TINAZOL

Keep out of the sight and reach of children

Do not store above 30 °C.

Do not take Tinazol after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tinazol contains ?

The active substance is tinidazole.

The other components are : maize starch, microcrystalline cellulose, sodium methylparahydroxybenzoate (E219), sodium propylparahydroxybenzoate (E217), talc, magnesium stearate, colloidal anhydrous silica, Film-coating : talc, hypromellose, titanium dioxide (E171), polyethylene glycol 6000.

What Tinazol looks like and contents of the pack

Box of 4 round white tablets packaged in PVC/Aluminium blister.

Tinazol® is a registered trademark

Property of Exphar s.a.. Zoning Industriel de Nivelles Sud, zone II, Av. Thomas Edison 105, 1402 Thines (Belgium).

Manufacturer

Gracure Pharmaceuticals Ltd.,

E-1105, RIICO Industrial area, Phase III, Bhiwadi, Alwar (Rajasthan) INDIA.

Medicinal product subject to medical prescription.

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