PACKAGE LEAFLET

TINIDAZOL

ATC code: J01XD02

PHARMACOTHERAPEUTIC GROUP:
Antibacterials. Imidazole derivatives.

COMPOSITION:
Tinidazole 500 mg in one film-tablet.

ACTION:
Tinidazol is a synthetic preparation from the imidazole group possessing antitrichomonadal and antiprotozoal effect. It provokes intracellular chemical reduction in the specific metabolism of the anaerobic microorganisms. It affects the spiral structure of DNA; it terminates the synthesis of nucleic acids that leads to cellular death.

The range of activity of tinidazol includes: *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia intestinalis*. It is active against *Gardinella vaginalis* and the most obligate anaerobic bacteria including: *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Bacteroides spp.*, *Clostridium spp.*, *Eubacterium spp.*, *Fusobacterium spp.*, *Peptococcus spp.*, *Peptostreptococcus spp.* and *Veillonella spp.*

Tinidazol is rapidly absorbed from gastrointestinal tract after oral reception. Maximal plasma concentrations are reached about 2 hours after the reception and are maintained 12 hours. It is bound to plasma proteins in about 12 %. It is
distributed in the tissues in therapeutic concentrations. It passes into the milk and via the blood-brain barrier. It is excreted predominantly in the urine and at a lower degree in the faeces (about 25% from the taken dose unchanged and about 12% as metabolites).

**INDICATIONS:**

Infections caused by susceptible to tinidazol microorganisms including anaerobic infections as well: endometrites, endomyometrites, tuboovarian abscess; non-specific vaginitis; urogenital trichomoniasis; respiratory infections (pneumonia, also aspiratory pneumonia); infections of the skin and the soft tissues; acute ulcerous gingivitis; lambliasis; intestinal amebiasis; hepatic amebiasis.

Postoperative infected wounds and for preoperative prevention and for prevention from postoperative anaerobic infections in surgical interventions.

**CONTRAINDICATIONS:**

Hypersensitivity to the preparation or to other imidazole derivatives. Deviations in the hematologic indicators, organic diseases of nervous system.

Children under 12 years of age.

Severe alterations of liver.

**ADVERSE REACTIONS/SIDE EFFECTS:**

The preparation is tolerated very well from most of the patients.

Sometimes it is possible to observe allergic reactions: skin rashes and itching.

Rarely - gastrointestinal complaints such as: nausea, vomiting, lack of appetite, diarrhoea, dry and bitter taste in the mouth, pseudomembranous colitis, which disappear quickly.
Some other possible symptoms are: dizziness, headache, tiredness, sleep disturbances, ataxia, depression, cramps, peripheral neuropathy, excessive excitement, desorientation. Very rarely: thrombophlebitis; leucopenia; vaginal candidosis, darkness of the urine, dysuria, urinary incontinence and cystitis.

DRUG AND NON-DRUG INTERACTIONS:

Antabuse reaction (red colour of skin, tachycardia) is manifested when alcohol or alcohol-containing drugs have been used. It enhances the activity of the coumarin anticoagulants - the tendency for bleeding is augmented. Adaptation of the anticoagulant dose is needed during the treatment and 8 days after its discontinuance.

PRECAUTIONS AND WARNINGS:

Alcohol use during the treatment is not recommended.

Discontinuance of the treatment is needed when neurologic disturbances such as dizziness and motor dyscoordination occur.

In case of trichomoniasis treatment of the both partners should be carried out simultaneously.

PREGNANCY AND BREAST-FEEDING:

The preparation is contraindicated in pregnant and lactating women. The milk concentration of the preparation is equal to that of the blood.

EFFECTS ON ACTIVE ATTENTION, DRIVING ABILITY AND OPERATION OF MACHINERY:

There are no data about influencing the attention, reflexes and motor reactions.
MODE OF ADMINISTRATION:

The dose regimen is individual.

For treatment of anaerobic infections in adults: a single dose of 2 g on the first day and a single dose of 1 g or two doses of 500 mg during the next days. The duration of treatment is from 5 to 7 days.

For nonspecific vaginites in women: a single dose of 2 g or twice daily of 1 g for 2 days.

For acute ulcerous gingivites in adults: a single dose of 2 g.

For urogenital trichomoniasis in adults (concomitant therapy of the both partners) a single dose of 2 g. For children a single dose of 50-75 mg/kg b.w.

For lambliaisis in adults: a single dose of 2 g; in children: a single dose of 50-75 mg/kg b.w.

For intestinal amebiasis in adults: 2 g daily for 2-3 days or twice daily of 500 mg for 5 days. The duration of treatment could be prolonged up to 10 days if there was no effect; in children of 12 years and over: 50-60 mg/kg daily dose for 3 days.

For hepatic amebiasis in adults: 1,5-2 g daily dose for 3-6 days; in children: 50-60 mg/kg once daily for 5 days.

For prevention from postoperative anaerobic infections in adults: a single dose of 2 g 12 hours before the surgical intervention.

The preparation should be taken with water after meal. If a dose is missed the next dose should be taken as soon as possible and the treatment continues according the prescribed schedule.
OVERDOSAGE:

Excitement, headache, tachycardia; in severe cases shock, hypotension, dyspnea, asthmatic symptoms. Depletion of the stomach content. Symptomatic treatment, antihistamine preparations, glucocorticoids, general reanimation measures.

DOSAGE FORM AND PACKAGES:

4 tablets of 500 mg in one package.

STORAGE:

In a dry and protected from light place at a temperature of 15-25°C.