

Trade Name:

Metrozole tablets

Composition:

Each tablet contains:

Metronidazole 250 mg

Pharmacological properties:

Metrozole is an oral synthetic antiprotozoal & antibacterial drug. It exerts antimicrobial effects in an anaerobic environment by the following possible mechanism: Once metronidazole enters the organism, the drug is reduced by intracellular electron transport proteins. Because of this alteration to the metronidazole molecule, a concentration gradient is maintained which promotes the drug's intracellular transport. Presumably, free radicals are formed which, in turn, react with cellular components resulting in death of the microorganism.

Pharmacokinetics:

Following oral administration, Metronidazole is well absorbed, with peak plasma concentrations occurring between one & two hours after administration. Plasma concentrations of Metronidazole are proportional to the administered dose. Oral administration of 250 mg or 500 mg produces peak plasma concentration of 6 mcg / ml & 12 mcg /ml respectively. Elimination half – life of Metronidazole is eight hours. The major route of elimination of Metrozole and its metabolites is via the urine (60-80% of the dose) with fecal excretion accounting for 6 – 15% of the dose .

Indications:

- Symptomatic Trichomoniasis in females & males .
- Asymptomatic Trichomoniasis in females . When the organism is associated with endocervicitis, cervicitis or cervical erosion.
- Amebiasis : acute intestinal amebiasis (amebic dysentery) & amebic liver abscess.
- Treatment of anaerobic infections caused by bacteroides such as peritonitis , intraabdominal abscess,skin & skin structure infections , Gynecologic infections (including endometritis , tubo – ovarian abscess & postsurgical vaginal cuff infection), Bacterial

septicemia , Bone & joint infections , central nervous system infections including meningitis and brain abscess , lower respiratory tract infections & endocarditis.

Contraindications:

Metrozole tablets are contraindicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives.

Warnings:

Metrozole should be administered with caution to patients with central nervous system diseases.

Precautions:

Patients with severe hepatic disease metabolize Metrozole slowly. Accordingly, for such patients, doses below those usually recommended should be administered cautiously .

Known or previously unrecognized candidiasis may present more prominent symptoms during therapy with Metrozole .

Care should be taken in patients receiving corticosteroids or to patients with predisposed edema.

Pregnancy:

- Oral Metrozole is contraindicated during the first trimester of pregnancy.
- In the second and third trimester should be used only if clearly needed.
- Pregnant patients if treated during the second or third trimester, the one day course of therapy shouldn't be used.

Lactation:

A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother as it is secreted in breast milk.

Drug interactions:

- Metrozole potentiates the anticoagulant effect of warfarin & other coumarin anticoagulants resulting in prolongation of prothrombin time

- Phenytoin or Phenobarbital may accelerate the elimination of Metrozole resulting in reduced plasma levels.
- In patients stabilized on relatively high doses of lithium, short – term oral Metrozole therapy has been associated with elevation of serum lithium & in a few cases, signs of lithium toxicity.
- Alcoholic beverages should not be consumed during Metrozole therapy & for at least one day afterward because abdominal cramps, nausea, vomiting, headache & flushing may occur.
- Metrozole should not be given to patients who have taken disulfiram within the last two weeks.
- Cimetidine may prolong half life and decrease plasma concentration of Metrozole.

Side effects:

The following side effects have been reported during therapy:

Nausea, headache, anorexia, urticaria, vomiting, metallic taste, epigastric distress, reversible leukopenia & proliferation of candida in the vagina, mouth dryness.

C.N.S: convulsive seizures, peripheral neuropathy, dizziness, vertigo, incoordination, ataxia, confusion, irritability, depression, weakness and insomnia

Overdosage:

Neurotoxic effects, including seizures & peripheral neuropathy have been reported after 5 to 7 days of doses of 6 to 10.4 gm every other day.

Treatment: There is no specific antidote for overdose , therefore, management of the patient should consist of symptomatic & supportive therapy.

Dosage & administration:

- **Amebiasis:**

Adults:

- For acute intestinal amebiasis (acute amebic dysentery) : 3 tablets, three times daily for 5 to 10 days.
- For amebic liver abscess: 2 or 3 tablets three times daily for 5 to 10 days.

Children:

35 to 50 mg / kg / 24 hours, divided into three doses, orally for 10 days.

- **Giardiasis:**

Adults:

Either 8 tablets daily for 3 days or 1 tablet, two or three times daily for 5 – 10 days.

Children:

25 – 35 mg / kg daily in two divided doses.

- **Trichomoniasis:**

- One-day treatment: 8 tablets given either as a single dose or in two divided doses of 4 tablets each given in the same day.
- Seven-day course of treatment: One tablet three times daily for seven consecutive days.
- Seven –day course gives results better than one day course.

- **Bacterial vaginosis:**

Two tablets twice daily for 7 days.

- **Clostridium difficile colitis :**

One tablet four times daily for 5 – 10 days.

- **Dental infections:**

One tablet three times daily for 3 – 7 days.

Therapeutic Category:

Antiprotozoal.

Legal Category:

Prescription only medicine.

Storage:

Store in a dry place in a temperature below 30° C and protect from light.

Package:

Box containing 20 tablets.

THIS IS A MEDICAMENT

Medicament is a product ,which affects your health and its consumption contrary to instructions is dangerous for you .

Follow strictly the doctor’s prescription ,the method of use and the instructions of the pharmacist who sold the medicament .

- *The doctor and the pharmacist are the experts in medicines ,their benefits and risks .*
- *Do not by yourself interrupt the period of treatment prescribed .*
- *Do not repeat the same prescription without consulting your doctor .*
- *Keep all medicaments out of reach of children .*

Council of Arab Health Ministers ,Union of Arab Pharmacists .