

Trade Name:

Metrozole Suspension

Composition:

Each 5 ml contains:

Benzoyl metronidazole 200 mg
(Equivalent to 125 mg metronidazole)

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 abs'cess

& 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 suspension is contraindicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives.

Side effects:

The following side effects have been reported during therapy: Nausea, headache, anorexia, urticaria, metallic taste, reversible leukopenia & proliferation of candida in the vagina, mouth dryness, convulsive seizures and peripheral neuropathy.

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 reduction of its 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.

Warning & Precautions:

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

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.

Pregnancy:

Oral Metrozole is contraindicated during the first trimester of pregnancy

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.

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) : 750 mg (2 Tablespoonful) three times daily *for* 5 to 10 days.
- For amebic liver abscess: 500 mg (2 dessertspoonful) or 750 mg (2 Tablespoonful) three times daily *for* 5 to 10 days.

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

- **Giardiasis:**

Adults:

Either 2 gm (8 dessertspoonful) daily *for* 3 days *or* 250 mg (1dessertspoonful) two *or* three times daily *for* 5 - 10 days.

Children:

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

- **Trichomoniasis:**

One-day treatment: 2 gm (8 dessertspoonful) given either as a single dose or in two divided doses of one gm (4 dessertspoonful) each given in the same day. Seven-day course of treatment: 250 mg (one dessertspoonful) three times daily for seven consecutive days.

Seven -day course gives results better than one day course.

Bacterial vaginosis:

500 mg (2 dessertspoonfuls) twice daily for 7 days.

Clostridium difficile colitis:

250 mg (one dessertspoonful) four times daily for 5 - 10 days.

Dental infections:

200 mg (one dessertspoonful) three times daily for 3 - 7 days.

Therapeutic Category:

Antiprotozoal.

Legal category:

Prescription only medicine.(POM)

Package:

Bottles of 120 ml.

Storage:

Store at a temperature below 30° C, protect from light.

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 .