

TRICOZOLE-250

METRONIDAZOLE 250MG TABLETS

COMPOSITION:

Each tablet contains: Metronidazole BP 250mg.

PROPERTIES:

Metronidazole is 5-nitroimidazole derivative with activity against protozoa and anaerobic bacteria, it also has a radio sensitizing effect on hypoxic tumor cells. Its mechanism of action is thought to involve interference with DNA by a metabolite in which the nitro group of Metronidazole has been reduced.

ABSORPTION AND FATE:

Metronidazole is readily absorbed following administration by mouth and bioavailability approaches 100%. Peak plasma concentrations of approximately 5 and 10 mcg per ml are achieved an average of 1 hour after single doses of 250 and 500mg respectively. Higher concentrations and consequently some accumulation occur when multiple doses are given. Absorption may be delayed, but it is not reduced overall by administration with food. Metronidazole is widely distributed. It appears in most tissues and fluids including bile, bone, breast milk, cerebral abscesses, saliva, seminal fluid and vaginal secretions and achieves concentrations similar to those in plasma. It crosses the placenta and rapidly enters the foetal circulation. No more than 20% is bound to plasma proteins. Metronidazole is metabolised in the liver by side chain oxidation and glucuronide formation. The principal oxidative metabolites are 1-(2-hydroxyethyl)-2-hydroxymethyl-5-nitroimidazole (the hydroxy metabolite) which has antibacterial activity and is detected in plasma and urine, and 2-methyl-5-nitroimidazole-1-acetic acid (acid metabolite) which has virtually no antibacterial activity and is often not detected in plasma but is excreted in the urine and is probably formed by intestinal flora. The plasma elimination half life of Metronidazole is about 8-hours, that of the hydroxy metabolite is slightly longer. The half-life of the Metronidazole is longer in neonates and patients with severe liver disease; that of the hydroxy metabolite is prolonged in patients with renal failure.

The majority of a dose of Metronidazole is excreted in the urine mainly as metabolites; as small amount appears in the faeces.

INDICATIONS AND DOSAGES:

Metronidazole is used in the treatment of trichomoniasis and amoebiasis and in the prophylaxis and treatment of anaerobic bacterial infections. It has activity against *Trichomonas vaginalis*, *Entamoeba histolytica*, *Giardia lamblia* and the causative organisms of acute ulcerative gingivitis.

Trichomoniasis:

Metronidazole is given by mouth in a dosage of 250mg 3 times a day for 7 days. Children may be given 10 to 15 mg per kg body weight daily in divided doses.

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Amoebiasis:

For treatment of intestinal and hepatic infections with *Entamoeba histolytica*; Metronidazole is given in a dosage of 400 mg to 1 g 3 times a day for 5 to 7 days. Children may be given 35mg to 50mg per kg body weight daily in divided doses.

Anaerobic infections:

Metronidazole is used alone or in conjunction with other antimicrobials in treatment of infections involving susceptible anaerobic organisms. It is also used to prevent post-operative anaerobic infections after surgery. The usual adult dose by mouth is 500 mg 3 times a day for at least 7 days; the corresponding dose for children is 3.7 to 7.5 mg per kg body weight every 8 hours.

UNDESIRABLE EFFECTS:

Metronidazole may cause headache, malaise, transient rashes, anorexia, nausea and gastro-intestinal disturbances. Consumption of alcohol increases nausea. The urine of patients taking larger doses of the drug is stained brown by a pigment that is yet to be positively identified. The pigment is almost certainly a metabolite of Metronidazole and seems to have no clinical significance.

PRECAUTIONS:

Alcohol should be avoided as it may provoke confusion or acute psychoses when used in association with Metronidazole. It should be used with caution in nursing mothers. Metronidazole may enhance the activity of warfarin and other anticoagulants.

CATEGORY: Prescription Only Medicine (P.O.M).

THERAPEUTIC CATEGORY: ATC: P01A (Antiprotozoal-amoebicide) and **J01K** (Other systemic antibiotics).

STORAGE: Store in a dry place below 30°C. Protect from light. Keep out of reach of children. Protect from crushing and mechanical shock.

SHELF LIFE: As per the product label.

PRESENTATION:

Tricozole tablets are available in bulk packs of 1000 tablets in securipack opaque plastic containers.

LICENCE HOLDER: LABORATORY & ALLIED LTD.



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