



Ornil®

Ornidazole

Description

Ornidazole (Ornil®) belongs to 5-nitroimidazole group of drugs. It is an antiprotozoal and antimicrobial agent for the treatment of infections due to *Trichomonas vaginalis*, *Entamoeba histolytica*, *Giardia lamblia* and certain anaerobic bacteria such as *Bacteroides* and *Clostridium* spp., *Fusobacterium* spp. and anaerobic cocci.

Mode of action

The antimicrobial activity of ornidazole is due to the reduction of the nitro group to a more reactive amine that attacks microbial DNA, brings about loss of helical structure of DNA and subsequent DNA breakage thus inhibiting further synthesis and causing degradation of existing DNA.

Pharmacokinetics

Ornidazole is readily absorbed from the gastrointestinal tract and peak plasma concentrations of about 30 mcg per ml have been achieved within 2 hours of a single dose of 1.5 gm, falling to about 9 mcg per ml after 24 hours and 2.5 mcg per ml after 48 hours. The plasma elimination half-life of ornidazole is 12 to 14 hours. Less than 15% is bound to plasma proteins. It is widely distributed in body tissues and fluids, including the cerebrospinal fluid. Ornidazole is metabolized in the liver and is excreted in the urine, mainly as conjugates and metabolites and to a lesser extent in the faeces; 85% of a single oral dose has been reported to be eliminated within 5 days, 63% in the urine and 22% in the faeces. 4% of the dose is excreted as unaltered substance in the urine.

Composition

Ornil® Tablet: Each film-coated tablet contains Ornidazole INN 500 mg.

Indications

Ornidazole is used in the treatment of hepatic and intestinal amoebiasis, giardiasis, trichomoniasis of urogenital tract and bacterial vaginosis. Also used in the treatment and prophylaxis of susceptible anaerobic infections in dental and gastrointestinal surgery & in other mixed aerobic-anaerobic infections. Ornidazole is also advocated in the management of *H. pylori* induced duodenal ulcer in combination with other drugs.

Dosage & administration

Amoebiasis: Adults: 500 mg twice daily for 5-7 days. Children: 25 mg/kg once daily for 5 to 10 days. *Amoebic dysentery:* Adults: 1.5 gm as a single dose for 3 days. Children: 40 mg/kg once daily for 3 days. *Giardiasis:* Adults: 1.5 gm once daily for 1-2 days. Children: 40 mg/kg daily for 2 days. *Trichomoniasis:* Adults: 1.5 gm as a single dose or 500 mg twice daily for 5 days. Sexual partner should be simultaneously treated. Children: 25 mg/kg as a single dose. *Bacterial vaginosis:* Adults: 1.5 gm once, or 500 mg once daily 5-7 days.

Contraindications

Hypersensitivity to this agent and other imidazoles.

Side effects

Side effects with ornidazole include dizziness, alone or in combination with other adverse reactions. The other side effects occurring to a lesser extent are nausea, pyrosis, intestinal spasms and metallic taste. Vertigo, fatigue and other discomforts such as loose stools, insomnia, skin rash and headache have also been reported.

Use in pregnancy & lactation

Extensive studies in various species have revealed no sign of any teratogenic or fetotoxic action of ornidazole. However, it is better to avoid treatment with ornidazole in early pregnancy.

Precautions

Cautions should be exercised in patients with diseases of the CNS e.g. epilepsy or multiple sclerosis. A health risk exists, among others in patients with liver disease, brain damage, in pregnant and nursing women and children in case of overdosage.

Drug interactions

In contrast to other nitroimidazole derivatives, ornidazole does not inhibit aldehyde dehydrogenates and is therefore not incompatible with alcohol. However, it potentiates the effect of coumarin type oral anticoagulants. Ornidazole prolongs the muscle relaxant effect of vecuronium bromide.

Storage

Store in a cool and dry place, protected from light.

Packaging

Ornil® Tablet: Each carton contains 10X2 tablets in blister pack.



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.

53151

