DESCRIPTION

Ornidazole is a 5-nitroimidazole derivative with antiprotozoal and antibacterial properties against anaerobic bacteria. Chemically, ornidazole is 1-Chloro-3-(2-methyl-5-nitroimidazol-1-yl)propan-2-ol. Giro is a green coloured, oblong, biconvex, film coated tablet, scored on one side and plain on the other.

COMPOSITION

Each film coated tablet contains:

Ornidazole ........ 500 mg
Colours: Quinoline Yellow, Brilliant Blue & Titanium Dioxide

PHARMACOLOGY

Its antimicrobial activity is due to the reduction of the nitro group to a more reactive amine that attacks microbial DNA, inhibiting further synthesis and causing degradation of existing DNA.¹

PHARMACOKINETICS²

Ornidazole is readily absorbed from the gastro-intestinal tract and peak plasma concentrations of about 30 mcg per ml have been achieved within 2 hours of a single dose of 1.5 g, 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 metabolised 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.³ Biliary excretion may be important in the elimination of ornidazole and its metabolites.

INDICATIONS

Used in the treatment of severe hepatic and intestinal amoebiasis, giardiasis, trichomoniasis of uro-genital tract and bacterial vaginosis. Also used in the treatment and prophylaxis of susceptible anaerobic infections in dental and gastrointestinal surgery.⁴ Ornidazole is also advocated in the management of H. pylori duodenal ulcer in combination with other drugs.

CONTRAINDICATIONS

Hypersensitivity to ornidazole and other imidazoles.
WARNINGS AND PRECAUTIONS
Special precautions are required in case of ataxia, vertigo, mental confusion and patients with neurological diseases. There is need for adjustment of dosage and dosage interval in patients with hepatic impairment. Modification of the usual dosage is not necessary in patients of renal failure however, additional post haemodialysis dose may be required in patients undergoing this procedure.

Usage in pregnancy
There is no evidence of ornidazole accumulation when used in pregnant women. Therefore, dosage regimen of ornidazole requires no adjustment during pregnancy. However, adequate clinical trials have not been conducted. Ornidazole should be prescribed only if the potential benefit justifies the potential risk to foetus/ neonate.

ADVERSE REACTIONS
The most frequently encountered side effect is 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.

DRUG INTERACTIONS
So far with ornidazole, disulfiram like reaction has not been reported on consumption of alcohol.

OVERDOSE AND TREATMENT
Overdosage may cause exacerbation of all the pharmacological side effects of ornidazole. Treat with supportive and symptomatic therapy.

DOSAGE AND ADMINISTRATION
Amoebiasis
Adults: 500 mg twice daily for 5-7 days
Children: 25 mg per kg once daily for 5 to 10 days

Amoebic dysentery
Adults: 1.5 g once daily for 3 days
Children: 40 mg per kg once daily for 3 days

Giardiasis:
Adults: 1.5 g once daily for 1-2 days
Children: 40 mg per kg for 2 days

Trichomoniasis
Adults: 1.5 g once or 500 mg twice daily for 5 days. Sexual partner should be simultaneously treated.

Bacterial vaginosis
Adults: 1.5 g once or 500 mg once daily for 5-7 days

Anaerobic bacterial infections
Initiate oral therapy as soon as possible after I.V. infusion.
Adults: 500 mg twice daily for 5 to 10 days
Children: 10 mg per kg twice daily

STORAGE INSTRUCTIONS
Store in a cool, dry and dark place.

REFERENCES

1. Mc Clain RM and Downing JC
   Reproduction studies in rats treated with ornidazole.
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3. Schwartz DE and Jeunet F
   Comparative pharmacokinetic studies of ornidazole and metronidazole in man.
4. Jokipii L and Jokipii AMM
   Treatment of Giardiasis: Comparative evaluation of Ornidazole and Tinidazole as a
   single oral dose.
   Gastroenterology, 1982;83:399-404