

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	METROREN TABLETS (Metronidazole 200mg)
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Pack Insert

METROREN

COMPOSITION

Tablet

Each Uncoated tablet contains
Metronidazole BP 200mg

Film Coated:

Each Film Coated Tablet Contains:
Metronidazole BP 200mg

Suspension:

Each 5ml contains
Metronidazole Benzoate
Equivalent to Metronidazole BP 200mg

PHARMACOLOGY

This nitro group of metronidazole is reduced in anaerobic bacteria and protozoa by the pyruvate phosphoroclastic reaction, in which the drug acts as a preferential electron acceptor. It has been assumed that the product of reduction of the nitro group of metronidazole interacts with the DNA with ultimate inhibition of nucleic acid synthesis and subsequent cell death. Moreover metronidazole has been shown to inhibit DNA synthesis and degrade existing DNA in *Clostridium bififormans*.

INDICATIONS

Symptomatic Trichoniasis, asymptomatic Trichomoniasis, intestinal amoebiasis, amoebic liver abscess, anaerobic bacterial infections, intra-abdominal infections, skin and skin structure infections, Central Nervous System (CNS) infections, lower respiratory tract infections, Endocarditis.

DOSAGE AND ADMINISTRATION

Trichomoniasis:

Adults: 200mg every 8 hours for 7 days or 400-500mg every 12 hours for 5-7 days or 2g as a single dose.

Children:

1-3 years: 50mg every 8 hours for 7 days

3-7 years: 100mg every 12 hours

7-12 year: 100mg every 8 hours

Amoebiasis

Adults:

For acute intestinal amoebiasis (acute amoebic dysentery): 750 mg orally three times daily for 5 to 10 days.

For amoebic liver abscess: 500 mg or 750 mg orally three times daily for 5 to 10 days.

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

Anaerobic Bacterial Infections

The usual adult oral dosage is 7.5 mg/kg every six hours (approx. 500 mg for a 70-kg adult). A maximum of 4 g should not be exceeded during a 24-hour period.

SIDE EFFECTS

Nausea, vomiting, unpleasant taste, furred tongue, and gastrointestinal disturbances, rashes, rarely drowsiness, headache, dizziness, ataxia, darkening of urine, erythema multiforme, pruritus, urticaria, angioedema, and anaphylaxis; also reported abnormal liver function tests, hepatitis, jaundice, thrombocytopenia, aplastic anaemia, myalgia, arthralgia, unprovoked or intensive therapy peripheral neuropathy, transient epileptiform seizures, and leucopenia.

WARNINGS

Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paraesthesia of an extremity, have been reported in patients treated with metronidazole. Metronidazole should be administered with caution to patients with central nervous system diseases.

CONTRAINDICATIONS

Metronidazole is contraindicated in patients with a prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives. In patients with trichomoniasis, metronidazole is contraindicated during the first trimester of pregnancy.

PRESENTATION

Jar of 1000 Uncoated Tablets

Jar of 1000 Film Coated Tablets

Blister pack of 10x10 Tablets

100ml Syrup

STORAGE

Store in a cool, dry place below 30°C

Protect from light. Keep out of reach of children.

MANUFACTURED BY
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