

LABGENTIL® TABLETS
SECNIDAZOLE 500MG TABLETS

COMPOSITION:

Each film coated tablet contains: Secnidazole 500mg

PROPERTIES:

- Secnidazole is a 5-nitroimidazole derivative. It has activity against anaerobic bacteria and protozoa with properties similar to those of metronidazole.
- Secnidazole is rapidly and completely absorbed after oral administration and has longer half life than commonly used drugs in this class with a half life of 20 hours or more hence effective in intestinal amoebiasis and bacterial vaginosis with a single dose.
- Mechanism / mode of action is not entirely clear, but is thought to involve reduction by bacterial 'nitroreductase' to an unstable intermediate which interacts with DNA effectively preventing further replication.

PHARMACOKINETICS:

- On oral administration, secnidazole is rapidly and completely absorbed.
- Peak concentrations of Secnidazole are reached within 3 hours and it has an absolute bioavailability close to 100%.
- In the group of Nitroimidazoles, it has the longest plasma elimination half life of about 25 hours (20 hours or more).
- On oral administration therapeutic blood concentrations are maintained for upto 72 hours.
- Major portion of Secnidazole is excreted slowly in the urine and the remaining portion undergoes slow metabolism in the liver by oxidation and conjugation with Glucuronic Acid.
- High concentrations are reached in the tissues rapidly and its plasma binding is only 10%.
- Secnidazole crosses the placental barrier and can be found in maternal milk.

INDICATIONS:

Treatment of: Intestinal and Extra-intestinal Amoebiasis.
Trichomoniasis.
Giardiasis.
Urogenital and bacterial vaginosis.

CONTRA-INDICATIONS:

Hypersensitivity to imidazole compounds.

USE IN PREGNANCY/LACTATION:

Not recommended to use during the first trimester of pregnancy or during lactation.

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PRECAUTIONS / INTERACTIONS:

1. Patients should be advised not to take alcohol during therapy, as co-administration may cause disulfiram-like side effects.
2. Doses should be reduced in patients with severe liver disease.
3. Blood test should be carried out before and after therapy in patients suffering from leucopenia.
4. Secnidazole increases the anti-coagulant effect of warfarin and therefore increases the risk of bleeding.

SIDE-EFFECTS:

Nausea, vomiting, stomach burn with metallic taste, dry mouth, glossitis, stomatitis, urticaria and numbness or tingling in the extremities.

DOSAGE AND ADMINISTRATION:

Given orally and during meals.

Intestinal amoebiasis:

Children: 30mg/kg daily in a single dose.

Adults: 4 tablets daily in a single dose or divided into several doses.

Period of therapy depends on the severity of infection and it may last for 1 – 3 days.

Hepatic amoebiasis:

Children: 30mg/kg daily in a single dose or as divided doses into 3 doses.

Adults: 3 tablets daily in a single dose or divided into several doses. Period of therapy depends on the severity of infection and it may last for 1 – 3 days.

Trichomoniasis: 4 tablets in a single dose.

LEGAL CATEGORY: Prescription Only Medicine (POM).

THERAPEUTIC CLASSIFICATION: P01AB07 Agents against amoebiasis and other protozoal diseases.

STORAGE CONDITIONS: Store in a dry place below 30°C. Protect from light.

Keep out of reach of children.

PRESENTATION: Blister pack of 4's.

SHELF LIFE: As per product label.

LICENCE HOLDER: LABORATORY & ALLIED LTD.

Date of Last Review: January 2017



Laboratory & Allied Ltd.

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