

1.6 Product Information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. Name of the medicinal product

Labgentil tablets

2. Qualitative and quantitative composition

Each film coated tablet contains: Secnidazole 500mg

3. Pharmaceutical form

Tablets

4. Clinical Particulars

4.1 Therapeutic Indications

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

4.2 Posology and method of 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 – 5 days.

Hepatic amoebiasis: 2:

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.

4.3 Contraindications

Hypersensitivity to imidazole compounds.

4.4 Special Warnings and Precautions for Use

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.

4.5 Interaction with other medicinal products and other forms of Interaction

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.

4.6 Pregnancy and Lactation

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

4.7 Effects on Ability to Drive and Use Machines

Impairment of vigilance, due to the presence of alcohol, can make driving of vehicles or the use of machines dangerous.

4.8 Undesirable Effects

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

4.9 Overdose and treatment

Not specified

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: P01AB07

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.

5.2 Pharmacokinetic properties

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 up to 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.

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- 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

5.3 Preclinical safety data

There is no pre-clinical data of relevance to a prescriber, which is additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Excipient	Reference Specification
White corn starch	BP
Microcrystalline cellulose	BP
Croscarmellose sodium	BP
Povidone K-30	BP
White corn starch (for paste)	BP
Tartrazine yellow soluble colour	IH
Sodium benzoate	BP
Purified water	BP
Croscarmellose sodium	BP
Purified talc	BP
Colloidal silicon dioxide	BP
Magnesium stearate	BP
Methocel (CPS)	BP
Titanium dioxide	BP
Tartrazine yellow lake colour	IH
Purified talc	BP
Polyethene glycol 6000	BP
Monopropylene glycol	BP
Acetone	BP
Isopropyl Alcohol	BP
Purified water	BP

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C in a dry place.

6.5 Nature and Contents of Container

Yellow, circular biconvex film coated tablets, scored on one side and plain on reverse. Packed in blisters of 4's and contained in a unit box, with literature insert.

6.6 Special precaution for disposal and other handling

No special requirements.

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7 Marketing Authorization Holder and Manufacturing Site Addresses

Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,

Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com.

Manufacturing Site Address:

Company Name: LABORATORY & ALLIED LTD

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Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com

8 Marketing Authorization Number:

KENYA: H2012/CTD313/095

9 Date of first Registration/ Renewal of the Registration:

KENYA: 2012 /2019

10 Date of revision of the text:

May 2019