SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Metroleb-125 Suspension**
1.2 Generic Name	:	**Metronidazole Oral Suspension BP**
1.3 Strength	:	**125mg/5ml**
1.4 Pharmaceutical Form	:	**Oral Suspension**

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each 5 ml. contains:

Metronidazole Benzoate	BP	
eq. to Metronidazole	BP	125mg.
Sod. Methyl Hydroxybenzoate	BP	5mg.
Sod. Propyl Hydroxybenzoate	BP	1mg.
Flavoured base		q.s.

Colour: Sunset Yellow FCF

3. PHARMACEUTICAL FORM

Suspension

Orange-colored flavored palatable suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Metronidazole (**Metroleb**) is indicated for the treatment of infections due to anaerobic bacteria, Fistulating Crohn's disease, Leg ulcers, and pressure sores, Bacterial vaginosis (notably Gardnerella vaginalis infection), Pelvic inflammatory disease, acute ulcerative gingivitis, Acute oral infections, Surgical prophylaxis, Invasive intestinal amoebiasis, Extra-intestinal amoebiasis (including liver abscess), Urogenital trichomoniasis, giardiasis.

4.2 Posology and method of administration

- **Anaerobic infections**
  Child 1 month: 7.5 mg/kg every 12 hrs usually treated for 7 days (for 10–14 days in Clostridium difficile infection).
  Child 2 months–11yrs: 7.5 mg/kg every 8 hrs (max. per dose 400 mg) usually treated for 7 days (for 10–14 days in Clostridium difficile infection).
  Child 12–17yrs: 400 mg every 8 hrs usually treated for 7 days (for 10–14 days in Clostridium difficile infection).
  Adult: 400 mg every 8 hrs, alternatively 500 mg every 8 hrs usually treated for 7 days (for 10–14 days in Clostridium difficile infection).
- **Fistulating Crohn's disease**
  Adult: 10–20 mg/kg daily in divided doses, usual dose 400–500 mg 3 times a day usually given for 1 month but no longer than 3 months because of concerns about peripheral neuropathy.
- **Leg ulcers and pressure sores**
  Adult: 400 mg every 8 hrs for 7 days.
- **Bacterial vaginosis (notably Gardnerella vaginalis infection)**
  Adult: 400–500 mg twice daily for 5–7 days, alternatively 2 g for 1 dose.
- **Pelvic inflammatory disease:**
  Adult: 400 mg twice daily for 14 days.
- **Acute ulcerative gingivitis**
  Child 1–2 yrs.: 50 mg every 8 hrs for 3 days.
  Child 3–6 yrs.: 100 mg every 12 hrs for 3 days.
  Child 7–9 yrs.: 100 mg every 8 hrs for 3 days.
  Child 10–17 yrs.: 200–250 mg every 8 hrs for 3 days.
  Adult: 400 mg every 8 hrs for 3 days.
- **Acute oral infections**
  Child 1–2 yrs.: 50 mg every 8 hrs for 3–7 days.
  Child 3–6 yrs.: 100 mg every 12 hrs for 3–7 days.
  Child 7–9 yrs.: 100 mg every 8 hrs for 3–7 days.
  Child 10–17 yrs.: 200–250 mg every 8 hrs for 3–7 days.
  Adult: 400 mg every 8 hrs for 3–7 days.

- **Surgical prophylaxis**
  Adult: 400–500 mg, to be administered 2 hrs before surgery, then 400–500 mg every 8 hrs if required for up to 3 doses (in high-risk procedures).
- **Invasive intestinal amoebiasis, Extra-intestinal amoebiasis (including liver abscess):** 5 days in intestinal infection (for 5–10 days in extra-intestinal infection).
  Child 1–2 yrs.: 200 mg 3 times a day.
  Child 3–6 yrs.: 200 mg 4 times a day.
  Child 7–9 yrs.: 400 mg 3 times a day.
  Child 10–17 yrs.: 800 mg 3 times a day.
  Adult: 800 mg 3 times a day.
- **Urogenital trichomoniasis**
  Child 1–2 yrs.: 50 mg 3 times a day for 7 days.
  Child 3–6 yrs.: 100 mg twice daily for 7 days.
  Child 7–9 yrs.: 100 mg 3 times a day for 7 days.
  Child 10–17 yrs.: 200 mg 3 times a day for 7 days, alternatively 400–500 mg twice daily for 5–7 days, alternatively 2 g for 1 dose.
  Adult: 200 mg 3 times a day for 7 days, alternatively 400–500 mg twice daily for 5–7 days, alternatively 2 g for 1 dose.
- **Giardiasis**
  Child 1–2 yrs.: 500 mg once daily for 3 days.
  Child 3–6 yrs.: 600–800 mg once daily for 3 days.
  Child 7–9 yrs.: 1 g once daily for 3 days.
  Child 10–17 yrs.: 2 g once daily for 3 days, alternatively 400 mg 3 times a day for 5 days. alternatively, 500 mg twice daily for 7–10 days.
  Adult: 2 g once daily for 3 days, alternatively, 400 mg 3 times a day for 5 days, alternatively 500 mg twice daily for 7–10 days.

4.3 Contraindications

Metronidazole (Metroleb) is contraindicated in case of hypersensitivity to nitroimidazoles, metronidazole.

4.4 Special warnings and special precautions for use

Metronidazole should be used with caution in patients with active or chronic severe peripheral and central nervous system disease due to the risk of neurological aggravation.

Hepatic and Renal Impairment: In cases of severe hepatotoxicity or acute hepatic failure metronidazole should therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. In Hepatic Impairment reduce the total daily dose to one-third, and give once daily. Renal insufficiency delays the excretion of metronidazole only to an unimportant degree. Delayed plasma clearance and prolonged serum half-life (Upto 30 hrs.) are to be expected in severe liver disease.

4.5 Interaction with other FPPs and Other forms of Interaction

Alcohol (beverage) potentially causes a Disulfiram-like reaction when given with Metronidazole. Antiepileptics (Phenobarbital, Primidone) are predicted to decrease the exposure to Metronidazole. Disulfiram increases the risk of acute psychoses when given Metronidazole. Metronidazole is predicted to increase the risk of Capecitabine, Fluorouracil, Alkylating Agents (Busulfan) toxicity. Metronidazole increases the anticoagulant effect of Coumarins.

4.6 Pregnancy and lactation

Pregnancy: In pregnancy high-dose regimens of Metronidazole should be avoided, use only if potential benefit outweighs the risk.

Lactation: In Breast Feeding with systemic use significant amount present in milk it is advised to avoid large single doses.

4.7 Effects on ability to drive and use machines

Patients should be warned about the potential for drowsiness, dizziness, confusion, hallucinations, convulsions, or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur.

4.8 Undesirable effects

Common or very common: Dry mouth, myalgia, nausea, oral disorders, taste altered vomiting.

Uncommon: Asthenia, headache, leucopenia (with long-term or intensive therapy).

Rare or very rare: Agranulocytosis, Angioedema, appetite decreased, drowsiness, ataxia, confusion, encephalopathy, diarrhea, epigastric pain, dizziness, epileptiform seizure (with long term or intensive therapy) hallucination, mucositis, pancytopenia, hepatic disorders, neutropenia meningitis aseptic, optic neuropathy, pancreatitis, peripheral neuropathy (with long term or intensive therapy), psychotic disorder.

Frequency not known: Depressed mood, hearing impairment.

4.9 Overdose & Treatment

Single oral doses of metronidazole, up to 12g have been reported in suicide attempts and accidental overdoses. Symptoms were limited to vomiting, ataxia, and slight disorientation. There is no specific antidote for metronidazole overdosage. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antibacterial; Antiprotozoal

ATC Code: J01XD01

Mechanism of action: Metronidazole is of the nitroimidazole class. It inhibits nucleic acid synthesis by disrupting the DNA of microbial cells. Metronidazole is reduced by low-redox-potential electron transfer proteins (e.g. nitro-reductases such as ferredoxin) to unidentified polar product(s) which lack the nitro group. The reduction product(s) appears to be responsible for the cytotoxic and antimicrobial effects of Metronidazole.

5.2 Pharmacokinetic properties

Metronidazole is rapidly and almost completely absorbed on administration peak plasma concentrations occur after 20 min to 3 hrs. The half-life of Metronidazole is 8.5 ± 2.9 hrs. Metronidazole is metabolized in the liver by side-chain oxidation and glucuronide formation. Approximately 80% of the substance is excreted in urine with less than 10% in the form of the unchanged drug substance. Small quantities are excreted via the liver. Elimination half-life is 6-10 hrs.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Excipients	Spec.
Sucrose	BP
Sod. Methyl Hydroxybenzoate (Sod. Methylparaben)	BP
Sod. Propyl Hydroxybenzoate (Sod. Propylparaben)	BP
Xanthan Gum	BP
Glycerin	BP
Liquid Sorbitol (Sorbitol Solution 70%)	BP
Saccharin Sodium	BP
Colloidal Anhydrous Silica (Colloidal Silicon Dioxide)	BP
Polysorbate-80	BP
Citric Acid Monohydrate	BP
Colour Sunset Yellow FCF 15985	IH
Essence Banana No.1	IH
Purified Water	BP

6.2 Incompatibilities

No sufficient data is available

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Protect from light. Keep container tightly closed. Keep out of reach of children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

100 ml in an amber-colored PET bottle in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

LEBEN LABORATORIES PVT. LTD.,
Business Address:

RO & Works	:	Plot No. L-4 & L-15, Phase-III, MIDC, AKOLA–444 104 (MS), INDIA Ph.:0091-724-2259401/02/03 & Fax: 0091-724-2258371 E-mail- export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com
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Country	:	INDIA

8. MARKETING AUTHORISATION NUMBER

AMD/12/2002 & AMD/6/2002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

a) Date of first authorization: 21/01/1989.
b) Date of latest renewal: 01/01/2018.

10. DATE OF REVISION OF THE TEXT

01/01/2023