



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

### **Patient Information Leaflet**

#### **1. Name of the Product**

Metronidazole oral suspension BP 125 mg/5ml

#### **2. Description of the Product**

Yellowish orange colour suspension.

#### **3. What is in the medicine?**

Metronidazole oral suspension BP 125 mg/5ml contains Metronidazole benzoate.

#### **4. Strength of the medicine**

Each 5 ml contains:

Metronidazole Benzoate BP Equivalent to

Metronidazole BP .....125 mg

Flavoured syrupy Base ..... q.s.

Colour: Sunset Yellow

#### **5. What is this medicine used for?**

Metronidazole Oral Suspension is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected as the pathogen.

Metronidazole Oral Suspension is active against a wide range of pathogenic micro-organisms, notably *Trichomonas vaginalis*, *Entamoeba histolytica*, *Giardia lamblia*, *Balantidium coli* and other species of bacteroides, fusobacteria, eubacteria, clostridia, *Gardnerella vaginalis* and anaerobic cocci. Metronidazole an antibiotic that is used to treat bacterial infections of the vagina, stomach, liver, skin, joints, brain and spinal cord, lungs, heart, or bloodstream.

Metronidazole is also used to treat trichomoniasis, a sexually transmitted disease caused by a parasite. Usually both sexual partners are treated at the same time, even if one has no symptoms.

Do not use metronidazole to treat any condition that has not been checked by your doctor.

It is indicated in

- Adults, Children and New-borns with a gestation age of over 40 weeks for:



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

- The treatment of septicaemia, bacteraemia, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis, peritonitis and post-operative wound infections from which one or more pathogenic anaerobes have been isolated.
- The prevention of post-operative infections caused by anaerobic bacteria particularly species of Bacteroides and anaerobic streptococci.
- Adults and Children over 10 years only for:
  - Bacterial vaginosis (also known as non-specific vaginitis, anaerobic vaginitis or Gardnerella vaginitis).
  - Acute dental infections (e.g. acute pericoronitis and acute apical infections).
  - Anaerobically infected leg ulcers and pressure sores.
- Adults and Children for:
  - Giardiasis
  - Acute ulcerative gingivitis.
- Children for
  - Eradication of Helicobacter pylori

#### **6. How much and how often should you use this medicine?**

ROUTE OF ADMINISTRATION: Oral

Shake the oral suspension (liquid). Measure a dose with the supplied measuring device (not a kitchen spoon). Oral suspension (Bottle of 100 ml). A measuring spoon (5 ml) corresponds to 125mg of metronidazole. (Metronidazole benzoate 200 mg Equivalent to Metronidazole 125 mg).

A: Prophylaxis: against anaerobic infection chiefly in the context of abdominal (especially colorectal) and gynecological surgery.

Dosage: 400mg at 8 hourly intervals during the 24 hours preceding the operation followed by postoperative intravenous or rectal administration until the patient is able to take Metronidazole Oral Suspension by mouth.

Children < 12 years: 20 – 30mg/kg as a single dose given 1 – 2 hours before surgery.

Newborns with a gestation age <40 weeks: 10mg/kg body weight as a single dose before operation.

Elderly: Caution is advised in the elderly, particularly at high doses, although there is limited information available on modification of drug.

**Module 1: Administrative Information and Product Information**



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

Anaerobic infections: The duration of a course of Metronidazole treatment is about 7 days but it will depend upon the seriousness of the patient's condition as assessed clinically and bacteriologically.

B: Treatment of established anaerobic infection:

800mg followed by 400mg at 8 hourly intervals.

Children > 8 weeks to 12 years of age: The usual daily dose is 20 – 30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours. The daily dose may be increased to 40mg/kg, depending on the severity of the infection. Duration of treatment is usually 7 days.

Children < 8 weeks of age: 15mg/kg as a single dose daily or divided into 7.5mg/kg every 12 hours.

### **7. When should you not take this medicine?**

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. This medicine contains sucrose in each ml. Patients with rare hereditary problems of fructose intolerance, or sucrase-isomaltase insufficiency should not take this medicine.

### **8. Undesirable Effects**

The frequency of adverse events listed below is defined using the following convention: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data). Frequency, type and severity of adverse reactions in children are the same as in adults.

Serious adverse reactions occur very rarely with standard recommended regimens. However, clinicians who contemplate continuous therapy for the relief of chronic conditions, for periods longer than those recommended are advised to consider the possible therapeutic benefit against the risk of peripheral neuropathy.

#### *Blood and lymphatic system disorders:*

Very rare:

agranulocytosis, neutropenia, thrombocytopenia and pancytopenia, often reversible on drug withdrawal, although fatalities have occurred.

Not known:

A moderate leucopenia has been reported in some patients but the white cell count has always returned to normal before or after treatment has been completed.

#### *Immune system disorders:*

Rare:

Anaphylaxis



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

Not known:	urticaria, angioedema and fever
<i>Metabolism and nutrition disorders:</i>	
Not known:	anorexia
<i>Psychiatric disorders:</i>	
Very rare:	psychotic disorders, including confusion and hallucinations
Not known:	depressed mood

*Nervous system disorders:*

Very rare:

- Encephalopathy (eg. confusion, fever, headache, hallucinations, paralysis, light sensitivity, disturbances in sight and movement, stiff neck) and subacute cerebellar syndrome (eg. ataxia, dysathria, gait impairment, nystagmus and tremor) have been reported very rarely which may resolve on discontinuation of the drug
- Drowsiness, dizziness, convulsions, headache, ataxia, inco-ordination of movement

Not known:

During intensive and/or prolonged metronidazole therapy a few instances of peripheral neuropathy or transient epileptiform seizures have been reported. In most cases neuropathy disappeared after treatment was stopped or when dosage was reduced.

- Aseptic meningitis has been reported

*Hepatobiliary disorders:*

Very rare:

- Abnormal liver function tests, increase in liver enzymes (AST, ALT, alkaline phosphatase), cholestatic or mixed hepatitis, and hepatocellular liver injury, jaundice and pancreatitis, reversible on drug withdrawal have been reported.
- Cases of liver failure requiring liver transplant have been reported in patients treated with metronidazole in combination with other antibiotic drugs.

*Skin and subcutaneous tissue disorders:*

Very rare:

skin rashes, pustular eruptions, acute generalised exanthematous pustulosis, pruritus, flushing  
Erythema multiforme may occur, which may be reversed on drug withdrawal. Stevens-Johnson syndrome or toxic epidermal necrolysis, fixed drug eruption.

Not known:

*Musculoskeletal, connective tissue and bone disorders:*

Very rare:

myalgia, arthralgia

*Renal and urinary disorders:*

Very rare:

darkening of the urine (due to metronidazole metabolite)

**Module 1: Administrative Information and Product Information**



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

### **9. What other medicine or food should be avoided whilst taking this medicine**

Patients should be advised not to take alcohol during metronidazole therapy and for at least 48 hours afterwards because of the possibility of a disulfiram-like (antabuse effect) reaction.

Psychotic reactions have been reported in patients who were using metronidazole and disulfiram concurrently. Some potentiation of anticoagulant therapy has been reported when metronidazole has been used with the warfarin type oral anticoagulants. Dosage of the anticoagulant may require reducing. Prothrombin time should be monitored. No interactions have been reported of the heparin type. Lithium retention accompanied by evidence of possible renal damage has been reported in patients treated simultaneously with lithium and metronidazole. Lithium treatment should be tapered or withdrawn before administering metronidazole. Plasma concentration of lithium, creatinine and electrolytes should be monitored in patients under treatment with lithium while they receive metronidazole. Patients receiving phenobarbital or phenytoin metabolise metronidazole at a much greater rate than normally, reducing the half-life to approximately three hours. Increased serum carbamazepine levels and toxicity have been seen in patients given concomitant metronidazole.

### **10. What should you do if you miss a dose?**

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **11. How should you keep this medicine?**

Keep this medicine out of the sight and reach of children.

Store in a dry place, below 30°C. Protect from light. Store in the original package and keep containers tightly closed.

Do not use the medicine after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **12. Signs and Symptoms of Overdosage**



**AURA LIFECARE PVT. LTD.**

**Product: Metronidazole oral suspension BP 125 mg/5 ml**

**MODULE: 1**

Symptoms were limited to vomiting, ataxia and slight disorientation. There is no specific antidote for metronidazole overdose. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted.

### **13. What to do when you have taken more than the recommended dosage**

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 overdose. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted.

### **14. Name/Logo of Manufacturer/Importer/Marketing Authorisation Holder**

Sun Enterprises LTD

BP 1952

Kigali, Rwanda

### **15. Care that should be taken while taking this medicine**

Regular clinical and laboratory monitoring (especially leucocyte count) are advised if administration of Metronidazole for more than 10 days is considered to be necessary and patients should be monitored for adverse reactions such as peripheral or central neuropathy (such as paraesthesia, ataxia, dizziness, convulsive seizures). There is the possibility that after *Trichomonas vaginalis* has been eliminated a gonococcal infection might persist. The elimination half-life of metronidazole remains unchanged in the presence of renal failure. The dosage of metronidazole therefore needs no reduction. Such patients however, retain the metabolites of metronidazole. The clinical significance of this is not known at present. In patients undergoing haemodialysis, metronidazole and metabolites are efficiently removed during an eight-hour period of dialysis. Metronidazole should therefore, be re-administered immediately after haemodialysis. No routine adjustment in the dosage of Metronidazole need be made in patients with renal failure undergoing intermittent peritoneal dialysis (IPD) or continuous ambulatory peritoneal dialysis (CAPD).

Metronidazole is mainly metabolised by hepatic oxidation. Substantial impairment of metronidazole clearance may occur in the presence of advanced hepatic insufficiency.



**AURA LIFECARE PVT. LTD.**

***Product: Metronidazole oral suspension BP 125 mg/5 ml***

***MODULE: 1***

Significant cumulation may occur in patients with hepatic encephalopathy and the resulting high plasma concentrations of metronidazole may contribute to the symptoms of encephalopathy.

Metronidazole should be administered with caution to patients with hepatic encephalopathy. The daily dosage may be reduced to one third and may be administered once daily.

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.

Patients should be warned that metronidazole may darken urine. Due to inadequate evidence on the mutagenicity risk in humans, the use of Metronidazole for longer treatment than usually required should be carefully considered. Cases of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use. In this population, metronidazole should therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. Liver function tests must be performed just prior to the start of therapy, throughout and after end of treatment until liver function is within normal ranges, or until the baseline values are reached. If the liver function tests become markedly elevated during treatment, the drug should be discontinued.

#### **16. Date of Revision of PIL**

July 2022