METROLE®

METRONIDAZOLE SYRUP 25 mg/ mL

1- DESCRIPTION:
Each mL of Metrole® contains 25 mg of metronidazole as metronidazole benzoate: 4g, carboxymethylcel-lu lose sodium, methylparaben, propylparaben, glycerin, sucralose, acesulfame potassium, propylene glycol, sorbitol solution, sodium phosphate monobasic, sodium phosphate dibasic, xanthan gum, orange flavor, microcrystalline cellulose, purified water.

2- INDICATIONS:
Metrole® contains metronidazole benzoate; a synthetic drug indicated for:
• Treatment of infections due to various protozoa such as amoeba, giardia lamblia, trichomonas vaginalis.
• Treatment of intestinal and hepatic amoebiasis.
• Prevention and treatment of infections due to anaerobic bacteria such as fusobacterium, clostridium.
• Treatment of acute ulcerative gingivitis.
• Pre and post-operative prophylaxis in gynecological and gastrointestinal surgery.

3- MECHANISM OF ACTION:
Once Metrole® enters the organism, the drug is reduced by intra-cellular electron transport proteins. Because of this alteration to the metronidazol molecule, a concentration gradient is created and maintained which promotes the drug's intracellular transport. In result, free radicals are formed which, in turn, react with cellular components resulting in death of bacteria and parasites.

4- DOSAGE AND ADMINISTRATION:
To be taken orally. Shake well before use.
The dosage depends on your age and the illness being treated. The usual dose is:
• For adults: 0.5-1.5 g/day
• For children: 20-40 mg/kg/day
The daily dose should be taken as two or three divided doses.
The duration of treatment depends on the infection being treated:
• Giardiasis treatment duration is 5 days.
• Ameobiasis treatment duration is 7 days.
• Vaginitis treatment duration is 7 days.
• Vaginitis due to trichomonas treatment duration is 10 days.

5- SIDE EFFECTS:
Side effects may include:
• Nausea, vomiting, diarrhea, abdominal cramps.
• Metallic taste in the mouth.
• Loss of appetite.
• Allergic reactions: itching, flushing, urticaria, fever, angioedema.
• Convulsion, headache.
• Confusion.
• Red brown urine coloration.
• At high dosage and/or during prolonged treatment: hematological disorders (in particular leucopenia) decrease after discontinuation of treatment.
• Peripheral sensory neuropathies may occur during prolonged treatment.

6· WARNINGS AND PRECAUTIONS:

Do not take Metrole® if you are allergic to the active substance or any of the other ingredients of this medicine.

Do not exceed the recommended dose. Tell your doctor:

- If you are taking other medicines containing metronidazole.
- If you are suffering or have ever suffered from any liver or kidney disease.
- If you are suffering or have ever suffered from any diseases of the nervous system.
- If you have anomalies of the blood formula.

Drug Interactions:

Tell your doctor or pharmacist If you are taking, have recently taken or might take any other medicines. These medicines and metronidazole can interfere with each other:

- Disulfiram (used to treat alcoholism)
- Warfarin (Anticoagulant)
- Lithium (used to treat depression)
- Cyclosporin (Immunosuppressant medication)

Pregnancy and breastfeeding:

Metrole® is contra-indicated during pregnancy and breastfeeding.

Tell your doctor if you are pregnant (especially if you are in the third trimester of pregnancy) or plan to become pregnant or are breastfeeding.

Metrole® passes the placenta and is found in the breast milk in concentrations corresponding to those in the mother's serum.

Metrole® and Alcohol:

Do not drink alcohol while you are taking Metrole® Drinking alcohol while using Metrole® might cause unpleasant side effects, such as nausea, vomiting, stomach pain and headache.

7- STORAGE CONDITIONS:

- Store in a dry cool place below 25°C.
- Protect from light.
- Keep out of reach of children.

B·PACKAGING AND VOLUME:

DESCRIPTION	CODE	SHELF LIFE
Metrole® **25 mg/mL 100mL**	**3072010**	**2years**

Manufactured by:

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