

**PATIENT INFORMATION LEAFLET:  
TROGYL PLUS TABLETS/SUSPENSION:  
{Metronidazole and Diloxanide furoate}**

*Read this leaflet carefully before you start taking this medicine.*

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

**In this leaflet:**

1. What Trogyl plus is and what it is used for
2. Before you use Trogyl plus
3. How to use Trogyl plus
4. Possible side effects
5. How to store Trogyl plus
6. Further information
7. Presentation

**1. WHAT IS TROGYL PLUS AND WHAT IS IT USED FOR?**

The name of the medicine is Trogyl plus. The active ingredients are Metronidazole BP and Diloxanide furoate. Trogyl plus is indicated for acute amoebic dysentery, acute and chronic intestinal amoebiasis, extra intestinal amoebiasis, hepatic and other systemic infections due to Entamoeba histolytica, Giardiasis.

Each tablet contains: Metronidazole 200mg BP.

Diloxanide furoate 250mg BP.

Each 5ml suspension contains: Metronidazole (as benzoate) 200mg BP.

Diloxanide furoate 250mg BP.

**2. BEFORE YOU USE TROGYL PLUS:**

Do not use Trogyl plus without medical advice:

- If you have had an allergy to any of the ingredients in the past.
- If you are on any other drugs.

**3. HOW TO USE TROGYL PLUS:**

Adults: 2 x 3 times daily

Children 2 – 5 years: one teaspoonful (5mls) 3 times daily for 5-10days

Children 5- 12 years: Two teaspoonful (10mls) 3 times daily for 5-10days OR

0.5-1 tablet 3 times daily

*Do not take a double dose to make up for a forgotten dose.*

**4. POSSIBLE SIDE EFFECTS:**

Like all medicines, Trogyl plus can have side effects though not everyone gets them.

Occasional mild gastrointestinal disturbances, flatulence, nausea, vomiting, metallic taste, headache, ataxia, urticaria, angioedema and darkening of urine may occur..

**Report this or any other side effects to your doctor or pharmacist.**

**5. HOW TO STORE TROGYL PLUS:**

Do not use Trogyl plus after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Trogyl plus should be stored in a cool place below 30°C, protected from direct sunlight and kept out of the sight and reach of children

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

**6. FURTHER INFORMATION:**

What Trogyl plus contains

The active substances in Trogyl plus preparations are metronidazole (as benzoate) and Diloxanide furoate.

Trogyl plus is a registered trademark of Biodeal Laboratories Ltd.

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd.

[regulatoryaffairs@biodealkenya.com](mailto:regulatoryaffairs@biodealkenya.com).

This product should be used on the advice of a doctor or pharmacist.

**7. PRESENTATION:**

Trogyl plus is available as follows:

**Tablets:** 10 x 10's Blisters in unit box

**Suspension:** 100mls and 60mls in amber glass bottles, in unit box.

Manufactured by:

Biodeal Laboratories Ltd,  
123, Lunga Lunga Road,  
P.O. Box 32040-00600, Nairobi Kenya.



**Prepared by:** Regulatory affairs

**Date prepared:** 2020

**BIODEAL LABORATORIES LIMITED  
NAIROBI, KENYA**

**1.5.4            MOCK-UPS AND SPECIMEN**

**APPLICATION DOSSIER FOR REGISTRATION  
OF TROGYL PLUS SUSPENSION**