

# **PROTOGYL**

## **PRESENTATION:**

### PROTOGYL SUSPENSION

#### **Each 5ml contains:**

Metronidazole Benzoate equivalent to Metronidazole IP 100 mg  
Flavored Syrup base q.s.

*Available in 50 ml Bottle Pack*

### PROTOGYL FORTE SUSPENSION

#### **Each 5ml contains:**

Metronidazole Benzoate equivalent to Metronidazole IP 200 mg  
Flavored Syrup base q.s.

*Available in 50 ml Bottle Pack*

### PROTOGYL FORTE TABLETS:

Each film coated tablet contains Metronidazole BP 400mg

*Available as 10 Tablets x 25 Blister Pack*

### PROTOGYL DF TABLETS

#### **Each film coated tablet contains:**

Metronidazole BP 400mg  
Diloxanide Furoate BP 500mg

*Available as 30 Tablets x 10 Blister Pack*

### PROTOGYL DF SUSPENSION

#### **Each 5ml contains:**

Metronidazole Benzoate equivalent to Metronidazole IP 100mg  
Diloxanide Furoate BP 125mg

*Available in 50ml Bottle Pack*

**CATEGORY:** *Antiamoebic*

## **AMOEBIASIS CAUSE & CYCLE:**

Amoebiasis has a world wide distribution. Poor environmental sanitation & low socioeconomic status are important factors in spread of the disease, which occurs due to fecal contamination of food & water.

Amoebic cyst reaching the intestine transforms into trophozoites. They live on the surface of colonic mucosa as commensals & pass into stools; serving to propagate the disease.

Occasionally, the trophozoites pass into blood streams & reach liver via portal vein and can cause amoebic liver abscess.

### **PHARMACOKINETICS:**

#### **Metronidazole**

Absorption:	Rapid & complete absorption
Distribution:	Body tissue & fluids
Metabolism:	Liver
Onset of Action:	Within few hours
Duration of Action:	8 hours

#### **Diloxanide Furoate**

Absorption:	Rapid
Excretion:	Urine

### **INDICATIONS:**

- ◆ Asymptomatic cyst passers
- ◆ *Active amoebic infection (dysentery)*
- ◆ Amoebic Hepatitis
- ◆ *Amoebic Liver abscess*
- ◆ *Giardiasis*
- ◆ Chronic intestinal amoebiasis
- ◆ Intestinal amoebiasis
- ◆ Postoperative anaerobic infection (Prophylaxis: Metronidazole)

***DF is very effective luminal amoebicide used alone for cyst passer or usually with MZ for other forms of amoebic infections.***

[MZ: *For both trophozoites & cysts* ]

### **MECHANISM OF ACTION:**

#### ***MZ***

In anaerobic microorganism MZ is converted to active form by reduction of its nitro group. This gets bound to DNA & prevents nucleic acid formation.

#### ***DF***

It directly kills trophozoites, responsible for production of cyst. No systemic antiamoebic activity is evident despite its absorption. *It is a drug of choice for mild intestinal & asymptomatic amoebiasis.*

#### **NOTE:**

Metronidazole is also used in:

- ◆ *Trichomonas vaginalis*
- ◆ *Giardia lumbia*
- ◆ *Bacteroides fragilis*

*Metronidazole was initially introduced as well tolerated effective agent for Trichomonas vaginalis & later found to be highly active amoebicide.*

**DOSAGE:**

***PROTOGYL DF***

**Adult:** 1 Protogyl DF tablet is usually recommended for 5-10 days or as directed by the physician.

**Children:** One teaspoonful 3 times daily for 5 days or as directed by the physician.

***PROTOGYL***

**Amoebiasis:**

**Adult:** 400-800mg 3 times daily for 5-10 days

**Children:** 36-50 mg/Kg/day in 3 divided doses for 10 days or as directed by the physician

**Giardiasis:**

**Adult:** 2gm once daily for 3 days or as directed by the physician

**Children:** 25-35 mg/Kg/day in 2 divided doses for 5-10 days or as directed by the physician

**SIDE EFFECTS:**

***MZ***

- ◆ Nausea, vomiting, diarrhea
- ◆ *Metallic taste*
- ◆ Headache, dry mouth
- ◆ Abdominal distress
- ◆ Urticaria, pruritus
- ◆ Ataxia, vertigo, dizziness, drowsiness

***DF***

- ◆ Nausea, flatulence
- ◆ *Itching, Skin rash*
- ◆ Anorexia

**WARNING:**

*Metronidazole has been shown to be carcinogenic in mice & possibly carcinogenic in rats. UNNECESSARY USE SHOULD THEREFORE BE AVOIDED.*

**PRECAUTIONS:**

**MZ**

- ◆ Severe renal dysfunction
- ◆ Severe obstructive hepatic disease
- ◆ Alcoholic cirrhosis

**Pregnancy:** *Use only if clearly needed, NOT RECOMMENDED for first trimester in pregnancy*

**Lactation:** Use with caution, should not be breast feed during treatment

**DF** [Not active in hepatic amoebiasis]

**Pregnancy:** [Contraindicated ]

**Lactation:** [Use with caution ]

**CONTRAINDICATIONS:**

**MZ**

- Active CNS disease
- Blood dyscrasias
- Hypersensitivity

**DF**

- Children under 2 years age

**DRUG INTERACTIONS AND/OR RELATED PROBLEMS:**

- Warfarin & other coumarin anticoagulant

[Potentiates anticoagulant effect, increasing prothrombin time by Metronidazole]

- **Alcohol**

[A disulfiram like reaction occurs: Abdominal cramps, nausea, vomiting, headache & flushing]

- Disulfiram

[Acute psychotic reaction or confusion state]

- Lithium

[Increase Lithium level]

- Phenobarbitone & Phenytoin

[Increase metabolism of Metronidazole]

For further information, please contact:

**Market Planning Department**



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