

# Flamyd®



Metronidazole Tablet & Solution for IV infusion

## Presentation

Flamyd® 250: Each film coated tablet contains Metronidazole BP 250 mg.  
Flamyd® 500: Each film coated tablet contains Metronidazole BP 500 mg.  
Flamyd® IV: Each 100 ml solution contains Metronidazole BP 500 mg.

## Description

Metronidazole is a member of the imidazole class of antibacterial agents and is classified therapeutically as an antiprotozoal and antibacterial agent. The intracellular targets of action of metronidazole on anaerobes are largely unknown. The 5-nitro group of metronidazole is reduced by metabolically active anaerobes, and studies have demonstrated that the reduced form of the drug interacts with bacterial DNA. However, it is not clear whether interaction with DNA alone is an important component in the bactericidal action of metronidazole on anaerobic organisms.

## Indications and Uses

### Flamyd tablet

1. The prevention of post-operative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci.
2. The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis and post-operative wound infections from which pathogenic anaerobes have been isolated.
3. Urogenital trichomoniasis in the female and in the male.
4. Bacterial vaginosis (also known as non-specific vaginitis, anaerobic vaginosis or Gardnerella vaginitis).
5. All forms of amoebiasis (intestinal and extra-intestinal disease and that of symptomless cyst passers).
6. Giardiasis.
7. Acute ulcerative gingivitis.
8. Anaerobically-infected leg ulcers and pressure sores.
9. Acute dental infections due to anaerobic organisms (eg. acute pericoronitis and acute apical infections).
10. *H. pylori* infection
11. Antibiotic Associated *Pseudomembranus colitis*

### Flamyd IV Infusion

1. The prevention of postoperative infections due to anaerobic bacteria
2. The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis and post-operative wound infections from which pathogenic anaerobes have been isolated.

## Dosages and Administration

### Flamyd tablet

Flamyd tablet may be taken before or after meal. Flamyd is to be taken in protozoal and other infections according to the following dosage regimens:

Indication	Duration in days	Adults & Children over 10 years	Children		
			7-10 years	3-7 years	1-3 years
Amoebic dysentery	5-10	750 mg t.i.d.	500 mg t.i.d.	250 mg q.i.d.	250 mg t.i.d.
Asymptomatic amoebiasis	5-10	500-750 mg t.i.d.	250-500 mg t.i.d.	250 mg q.i.d.	250 mg t.i.d.
Hepatic and extraintestinal amoebiasis	5-10	500-750 mg t.i.d.	250-500 mg t.i.d.	250 mg q.i.d.	250 mg t.i.d.
Giardiasis	3	2 g once daily	1g once daily	750 mg once daily	500 mg once daily
Trichomoniasis	7	250 mg t.i.d. or 2 g single dose	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
	1	2 g single dose	-	-	-
Vincent's infection (Ulceration of mucous membrane of mouth)	3	250 mg t.i.d. or 500 mg b.i.d.	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
	3	250 mg t.i.d.	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
Severe dental infection	3	500 mg t.i.d.	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
Anaerobic infection	7	500 mg t.i.d.	7.5 mg/kg body weight t.i.d.		
Postoperative anaerobic infection (especially in abdominal or gynaecological surgery)	7	500 mg t.i.d. before and after operation	7.5 mg/kg body weight t.i.d.		
	7	500 mg b.i.d.	-		
Bacterial Vaginosis	1	2 g as a single dose	-		
	7	500 mg t.i.d.	-		
Leg ulcers	7	500 mg t.i.d.	-		
Pressure sores	7	500 mg t.i.d.	-		
<i>H. pylori</i> infection	7	500 mg b.i.d.	-		
Antibiotic Associated <i>Pseudomembranus colitis</i>	7	500 mg b.i.d.	-		

### Flamyd IV Infusion

Flamyd injection should be infused intravenously at an approximate rate of 5 ml/min. Oral medication should be substituted as soon as feasible. Treatment for 7 days should be satisfactory for most patients, but the physician might decide to prolong treatment.

### For bacterial infections

Adults: 500 mg (100 ml) 8 hourly.  
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.

### For treatment before and during surgery

Adults: 500 mg (100 ml) shortly before operation, repeated 8 hourly.  
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.

### Contraindications

Metronidazole is contraindicated in patients with a history of hypersensitivity to Metronidazole or other Nitroimidazole derivatives.

### Precautions

Metronidazole should be given with caution in the following conditions- anaemia or other blood disorders, liver disease, disease of the nervous system, seizures etc.

### Side-effects

Pain, tenderness, redness, or swelling over vein in which the medicine is given. Other side-effects are unsteadiness, fever or chills, sore throat, headache, numbness, tingling pain or weakness in the hands or feet, pain, seizures, skin itching, unusual tiredness or weakness, vaginal irritation or discharge.

### Use in pregnancy & lactation

Pregnancy category B.

Studies have not been done in humans. Metronidazole has not been shown to cause birth defects in animal studies; however, use is not recommended during the first trimester of pregnancy. Use is not recommended in nursing mothers since metronidazole passes into the breast milk.

### Drug interactions

Metronidazole shows drug interaction with the followings: Alcohol or Alcohol-containing beverages, Barbiturate, Carbamazepine, Cimetidine, Disulfiram, Fluorouracil, Lithium, Methadone, Phenytoin, Warfarin etc.

### Instructions for the Use of Flamyd Injection

1. Check the bag for minute leaks by squeezing the inner bag firmly. If leaks are found, or if the seal is not intact, discard the solution.
2. Do not use if the solution is cloudy or a precipitate is present.
3. Do not use flexible bags in series connections.
4. Close flow control clamp of administration set.
5. Remove cover from port at bottom of bag.
6. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
7. Suspend bag from hanger.
8. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of Flamyd Injection.
9. Open flow control clamp to expel air from set. Close clamp.
10. Regulate rate of administration with flow control clamp.

### Commercial Pack

Flamyd® 250: Each box contains 10 blister strips of 10 film coated tablets.  
Flamyd® 500: Each box contains 10 blister strips of 10 film coated tablets.  
Flamyd® IV: Each box contains 1 bag of 100 ml solution for intravenous infusion.

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