

Florazol

Metronidazole BP 400 mg Tablet
& 200 mg/5 ml Suspension

Florazol (Metronidazole) is a member of the imidazole class of antibacterial drug and is classified therapeutically as an antiprotozoal agent. The 5-nitro group of Metronidazole is reduced by anaerobes metabolically. Studies have demonstrated that the reduced form of this drug interacts with DNA and gives bactericidal action of Metronidazole.

COMPOSITION

Florazol Tablet: Each film coated tablet contains Metronidazole BP 400 mg.

Florazol Suspension: Each 5 ml suspension contains Metronidazole Benzoate BP equivalent to Metronidazole 200 mg.

INDICATION

It is indicated in the treatment of following diseases:

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, pelvic abscess, pelvic cellulitis and post-operative wound infections caused by anaerobes.
3. In the treatment of urogenital trichomoniasis.
4. Bacterial vaginosis (also known as non-specific vaginitis).
5. All forms of amoebiasis (intestinal, 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.
10. Antibiotic associated pseudomembranus colitis.

DOSAGE AND ADMINISTRATION

It is to be taken in protozoal and other infections according to the following dosage regimens:

Infection	Duration in days	Adults & Children over 10 yrs	Children		
			7-10 yrs	3-7 yrs	1-3 yrs
Trichomoniasis *	7	200 mg tid or 400 mg bid	100 mg tid	100 mg bid	50 mg tid
	2	800 mg in the morning and 1-2 gm at night	—	—	—
	1	2 gm as a single dose	—	—	—
Intestinal amoebiasis	5	800 mg tid	400 mg tid	200 mg qid	200 mg tid
Extra-intestinal & Asymptomatic amoebiasis	5-10	400-800 mg tid	200-400 mg tid	100-200 mg qid	100-200 mg tid
Giardiasis	3	2 gm once daily	1 gm once daily	600-800 mg once daily	500 mg once daily
Acute ulcerative gingivitis	3	200 mg tid	100 mg tid	100 mg bid	50 mg tid
Acute dental infections	3-7	200 mg tid	—	—	—
Bacterial Vaginosis	7	400 mg bid	—	—	—
	1	2 gm as a single dose			
Leg ulcers and pressure sores	7	400 mg tid	—	—	—
Anaerobic infections	7	800 mg initially and then 400 mg tid	7.5 mg/kg tid	7.5 mg/kg tid	7.5 mg/kg tid
Surgical prophylaxis	1	400 mg tid started 24 hours before surgery	7.5 mg/kg tid	7.5 mg/kg tid	7.5 mg/kg tid

* Concomitant treatment of sexual partner is recommended.

SIDE EFFECT

Metallic taste, nausea, vomiting, diarrhoea, drowsiness, rashes may be observed during treatment.

PRECAUTION

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

CONTRAINDICATION

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

DRUG INTERACTION

Metronidazole has been found to interact with alcohol, warfarin, phenytoin, phenobarbitone, fluorouracil, disulfiram, lithium and cimetidine.

USE IN PREGNANCY AND LACTATION

US FDA Pregnancy Category of Metronidazole is B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Metronidazole have been shown to be excreted in human milk. So, caution should be exercised when Metronidazole is administered to a nursing woman.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

Florazol 400 Tablet: Each box contains 200's tablets in Alu-PVC blister pack.

Florazol Suspension: Each amber PET bottle contains 60 ml suspension.

Manufactured by:

NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.