Filmet®

(Metronidazole IV Infusion)

DESCRIPTION

Filmet is a sterile, pyrogen free, isotonic formulation for intravenous administration in susceptible life threatening infections. Each 100ml solution contains Metronidazole USP 500mg. Metronidazole is a nitroimidazole with antiprotozoal and antibacterial actions. It is highly effective against *Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia.* It has a bactericidal action against a wide range of pathogenic anaerobic microorganisms particularly species of *Bacteroides, Fusobacteria, Clostridia, Eubacteria, Anaerobic Cocci* and *Gardnerella vaginalis.*

INDICATIONS

Filmet is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected to be the causes. It is particularly suited for patients who can not retain oral medication and for patients in whom desired serum concentration have to be attained rapidly and reliably.

Filmet is indicated :

I . In the prevention of post operative infections due to anaerobic bacteria.

2. In the treatment of
   a. *Intra abdominal infections* - appendicitis, cholecystitis, peritonitis, liver abscess and post operative wound infections;
   b. *Gynaecological and obstetrical infections* - puerperal sepsis, pelvic cellulitis, pelvic peritonitis;
   c. *Respiratory infections* - necrotizing pneumonia, empyema, lung abscess;
   d. *Central Nervous System infections* - meningitis, brain abscess;
   e. *Miscellaneous infections* - septicaemia, bacteremia, osteomyelitis, gas gangrene.

DOSAGE AND ADMINISTRATION

Filmet may be diluted with appropriate volumes of normal saline, dextrose-saline, dextrose 5% w/v or potassium chloride (20 and 40 mmol) infusions.

For prophylaxis and treatment of anaerobic infections	Adults	Children
Dose	100 ml (500 mg) immediately before, during or after operation, repeated 8 hourly	1.5 ml (7.5 mg) per kg body weight every 8 hours
Duration	Treatment for 7 days should be satisfactory for most patients but depending on clinical and bacteriological assessments, the physician may decide to prolong the treatment	
Infusion rate	Filmet should be infused at an approximate rate of 5 ml/minute	

ADVERSE EFFECTS

Serious adverse reactions occur very rarely with standard recommended regimens. Unpleasant taste in the mouth, furred tongue, nausea, vomiting or other gastrointestinal disturbances have been reported. Urticaria, skin rash, pruritus, angioedema and rarely anaphylaxis have occurred. Drowsiness, dizziness, headache, ataxia and darkening of the urine (due to metabolites) have been reported rarely. Peripheral neuropathy and/or transient epileptiform seizures have occurred during prolonged or intensive treatment but in most cases neuropathy disappears on cessation of therapy. A moderate, reversible leucopenia has been reported in some patients.

CONTRAINDICATIONS

Known hypersensitivity to metronidazole.

PRECAUTIONS

Regular clinical and laboratory monitoring are advised if administration of Filmet for more than 10 days is considered to be necessary. Metronidazole should be administered with caution to patients with hepatic encephalopathy. Caution is advised in patients with active disease of the central nervous system other than brain abscess. The consumption of alcohol during metronidazole therapy should be avoided since there could be a disulfiram-like reaction.

USE IN PREGNANCY& LACTATION

There is inadequate evidence of the safety of metronidazole in pregnancy. Metronidazole is excreted in milk and no adverse effects in the newborn have been reported. Filmet should therefore be given during pregnancy or during lactation only when the physicians consider it essential.

WARNING

Infusion of fluid should be immediately discontinued if rigor arises for any reason during the process. Do not use if the solution is cloudy, contains particles or after expiry date.

PHARMACEUTICALPRECAUTIONS

Store at controlled room temperature. Protect from light. This Infusion is not intended for multi-dose use.

PACKAGING

Filmet is available in 100 ml polyethylene bottle containing 500 mg metronidazole USP.

BEXIMCO PHARMA
Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
TONGI, BANGLADESH
® REGISTERED TRADEMARK 190705