

# Metyl® IV

Metronidazole

## Description

Metronidazole IV (Metyl® IV) infusion is a sterile, pyrogen free, isotonic, ready to use solution requiring no dilution or buffering prior to intravenous administration in susceptible life threatening infections. Metronidazole is a 5-nitroimidazole derivative that has extremely broad spectrum activity against protozoa & anaerobic bacteria. It is active against a wide range of pathogenic micro-organisms notably species of *Bacteroides*, *Fusobacteria*, *Clostridia*, *Eubacteria*, *Anaerobic cocci*, *Gardnerella lamblia*, *Balantidium coli* and the causative organisms of acute ulcerative gingivitis.

## Mode of action

Metronidazole is converted to reactive metabolites by the redox enzyme pyruvate-ferredoxin oxidoreductase. Here, the nitro group of metronidazole is chemically reduced by ferredoxin (or a ferredoxin-linked metabolic process) to a reactive intermediate which causes the loss of helical structure of DNA, strand breakage and impairment of DNA function. So, nucleic acid synthesis is inhibited. Thus, causes the cell death of Bacteria.

## Composition

**Metyl® IV 100 ml infusion:** Each 100 ml contains Metronidazole BP 500 mg.

## Indications

It is indicated in

- The prevention of Post-operative infections due to anaerobic bacteria, particularly species of *bacteroides* and anaerobic *Streptococci* in case of intraabdominal infections, gynaecological and obstetrical infections, respiratory infections etc.
- The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotising, pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulites, and post-operative wound infections from which pathogenic anaerobes have been isolated.
- Urogenital trichomoniasis in the female (trichomonal vaginitis) and in the male.
- Bacterial vaginosis (also known as non specific vaginitis, anaerobic vaginosis or *Gardnerella* vaginitis).
- All forms of amebiasis (intestinal and extra-intestinal disease and that of symptomless cyst passers).
- Giardiasis.
- Acute ulcerative gingivitis.
- Anaerobically infected leg ulcers and pressure sores.
- Acute dental infections (e.g. acute pericoronitis and acute apical infections).

## Dosage and administration

**Metyl® IV** infusion requires no dilution and should not be mixed with any other drugs prior to administration.

### Adults and children over 12 years:

Infuse 500 mg 8 hourly at a 5ml/minute and a maximum of 4g should not be exceeded during a 24-hour period. Treatment for 7 days is sufficient for patients, but treatment can be extended, especially for cases where reinfection is likely. For surgical prophylaxis, administration shortly before surgery should be followed by 8-hourly doses for the next 24 hours.

### Children under 12 years:

7.5mg/kg body weight/day every 8 hours at a rate of 5ml/minute.  
Or as directed by the physician.

## Contraindications

Patients with evidence of a history of blood dyscrasias should not receive the drug, since upon occasion a mild leucopenia has been observed during its administration. Metronidazole is also contraindicated to the patients with active organic disease of the central nervous system and hypersensitive to Metronidazole or other Imidazoles.

## Side effects

Adverse reaction occurs very rarely with standard recommended regimens. Unpleasant taste in mouth, furred tongue, nausea, vomiting, gastro-intestinal disturbance, urticaria and angioedema occur occasionally. Anaphylaxis may occur rarely.

## Use in pregnancy & lactation

There is inadequate evidence of safety of Metronidazole in pregnancy. It should not therefore be given during pregnancy or during lactation unless the physician considers it essential this circumstance the high dosage regimens are not recommended.

## Precautions

Regular clinical and laboratory monitoring are advised of administration of Metronidazole IV infusion 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.

## Drug interactions

Metronidazole interacts with warfarin and increases the blood level of warfarin, causing a hypothrombinemic effect, it is postulated that Metronidazole inhibits oxidation of warfarin and therefore impairs total body clearance of warfarin. Cimetidine prolongs the half-life to Metronidazole through the reduction of its total plasma clearance.

## Over dosage

Single doses of metronidazole, up to 15 g, have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting, and ataxia.

## Storage

Store in a place which protects from heat & light.

## Packaging

**Metyl® IV infusion:** 100 ml sterile solution in clear glass bottle.

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