

Metco® IV

Metronidazole BP Intravenous Infusion

DESCRIPTION

Metco® IV is a intravenous preparation of Metronidazole. Metronidazole is a synthetic antibacterial compound. Disposition of Metronidazole in the body is similar for both oral and intravenous dosage forms, with an average elimination half-life in healthy humans of eight hours.

Metco® IV is an antimicrobial drug that is primarily active against obligate anaerobic microorganisms, both bacteria & protozoa. The 5-nitro group undergoes reductive transformation to an active intermediate which then exerts an inhibitory or lethal effect against DNA. Not only is DNA synthesis inhibited but the reduced metabolite also causes a loss of the helical structure of DNA with subsequent DNA strand breakage. The structure of the intermediate has not been determined. Other reduction-oxidation processes within anaerobic organism may also be inhibited (the phosphoroclastic reaction in clostridia), which also contribute to cell death. In vitro, **Metco® IV** demonstrates a consistently rapid bactericidal effect with the minimal bactericidal concentration approximating very closely to the minimal inhibitory concentration.

INDICATIONS

- **Intra-Abdominal Infections:** including peritonitis, intra-abdominal abscess and liver abscess, caused by Bacteroides species including the *B. fragilis* group (*B. fragilis*, *B. distasonis*, *B. ovatus*, *B. thetaiaomicron*, *B. vulgatus*), Clostridium species, Eubacterium species, Peptococcus species and Peptostreptococcus species.
- **Skin and Skin Structure Infections:** caused by Bacteroides species including the *B. fragilis* group, Clostridium species, Peptococcus species, Peptostreptococcus species and Fusobacterium species.
- **Gynecologic Infection:** including endometritis, endomyometritis, tubo-ovarian abscess and postsurgical vaginal cuff infection, caused by Bacteroides species including the *B. fragilis* group, Clostridium species, Peptostreptococcus species and Fusobacterium species.
- **Bacterial Septicemia:** caused by Bacteroides species including the *B. fragilis* group and Clostridium species.
- **Bone and Joint Infections:** as adjunctive therapy, caused by Bacteroides species including the *B. fragilis* group.
- **Central Nervous System (CNS) Infections:** including meningitis and brain abscess, caused by Bacteroides species including the *B. fragilis* group.
- **Lower Respiratory Tract Infections:** including pneumonia, empyema and lung abscess, caused by Bacteroides species including the *B. fragilis* group.
- **Endocarditis:** caused by Bacteroides species including the *B. fragilis* group.
- **Prophylaxis:** The prophylactic administration of Metronidazole Injection preoperatively, intraoperatively and postoperatively may reduce the incidence of postoperative infection in patients undergoing elective colorectal surgery which is classified as contaminated or potentially contaminated. Prophylactic use of Metronidazole Injection should be discontinued within 12 hours after surgery.

DOSAGE AND ADMINISTRATION

In elderly patients the pharmacokinetics of Metronidazole may be altered and therefore monitoring of serum levels may be necessary to adjust the Metronidazole dosage accordingly.

Treatment of Anaerobic Infections: The recommended dosage schedule for adults is:

- **Loading Dose:** 15 mg/kg infused over one hour (approximately 1 g for a 70 kg adult).
- **Maintenance Dose:** 7.5 mg/kg infused over one hour every six hours (approximately 500 mg for a 70 kg adult). The first maintenance dose should be instituted six hours following the initiation of the loading dose. A maximum of 4 g should not be exceeded during a 24-hour period.
- Patients with severe hepatic disease metabolize Metronidazole slowly, with resultant accumulation of Metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously. Close monitoring of plasma Metronidazole is recommended.
- The dose of Metronidazole Injection should not be specifically reduced in anuric patients since

accumulated metabolites may be rapidly removed by dialysis.

- The usual duration of therapy is 7 to 10 days; however, infections of the bone and joint, lower respiratory tract and endocardium may require longer treatment.
- **Prophylaxis:** For surgical prophylactic use, to prevent postoperative infection in contaminated or potentially contaminated colorectal surgery, the recommended dosage schedule for adults is:
 - 15 mg/kg infused over 30 to 60 minutes and completed approximately one hour before surgery; followed by
 - 7.5 mg/kg infused over 30 to 60 minutes at 6 and 12 hours after the initial dose.

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, and because metronidazole is a carcinogen in rodents, these drugs should be used during pregnancy only if clearly needed.

Nursing Mothers

Metronidazole is secreted in breast milk in concentrations similar to those found in plasma. So these drugs should be used during lactation only if clearly needed.

SIDE-EFFECTS

- **Gastrointestinal:** Nausea, vomiting, abdominal discomfort, diarrhea and an unpleasant metallic taste.
- **Hematopoietic:** Reversible neutropenia (leukopenia).
- **Dermatologic:** Erythematous rash and pruritus.
- **Central Nervous System:** Headache, dizziness, syncope, ataxia and confusion.
- **Local Reactions:** Thrombophlebitis after intravenous infusion. This reaction can be minimized or avoided by avoiding prolonged use of indwelling intravenous catheters.

CONTRAINDICATIONS

Metronidazole Injection is contraindicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives

PRECAUTIONS

- Patients with severe hepatic disease metabolize Metronidazole slowly, with resultant accumulation of Metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously.
- Administration of solutions containing sodium ions may result in sodium retention. Care should be taken when administering Metronidazole Injection to patients receiving corticosteroids or to patients predisposed to edema.
- Known or previously unrecognized candidiasis may present more prominent symptoms during therapy with Metronidazole Injection and requires treatment with a candidal agent.
- Prescribing Metronidazole Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

PHARMACEUTICAL PRECAUTIONS

Keep in dry place & away from light. Keep out of reach of children.

PACKAGING

Metco® IV Infusion:

Bottle containing 100 ml IV infusion, which contains Metronidazole BP 500 mg (5 mg/ml).



Manufactured by

ESKAYEF BANGLADESH LIMITED

GAZIPUR, BANGLADESH

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