Biozyl IV

Metronidazole 0.5% W/V

DESCRIPTION

BIOZYL IV is a preparation of Metronidazole which is an antimicrobial and antiprotozoal agent, particularly effective against anaerobic bacteria and protozoa. It is an anti-infectious drug belonging to the pharmaco-therapeutic group of nitroimidazole derivatives, which have effect mainly on strict anaerobes. Metronidazole is very active against three clinically important protozoa Trichomonas vaginalis, Giardia lamblia & Entamoeba histolytica and anaerobic bacteria-Bacteroides fragilis & related species: Fusobacterium, Peptococcus, Peptostreptococcus, Gardnerella vaginalis and Campylobacter species.

INDICATIONS

BIOZYL IV is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected to be the causes. Biozyl IV is active against a wide range of pathogenic micro-organisms notably species of Bacteroides, Fusobacteria, Clostridia, Eubacteria, anaerobic cocci and Gardnerella vaginalis.

BIOZYL IV is indicated in adults and children for the following indications:

- The prevention of post-operative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci.
- The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotizing pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis and postoperative wound infections from which susceptible pathogenic anaerobes have been isolated.

DOSAGE AND ADMINISTRATION

BIOZYL IV should be infused intravenously at an approximate rate of 5 ml/minute (or one bottle infused over 20 to 60 minutes). 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.

USE IN PREGNANCY AND LACTATION

Metronidazole is pregnancy category B. There is inadequate evidence of safety of metronidazole in pregnancy. Therefore metronidazole should not be given during pregnancy unless clearly necessary. Metronidazole is excreted in breast milk. During lactation either breast feeding or Metronidazole should be discontinued.

SIDE EFFECTS

The side effects of metronidazole are nausea, diarrhea, vomiting, constipation, indigestion, loss of appetite, abdominal pain, dry mouth, furred tongue, unpleasant metallic taste, dark urine and painful urination.

CONTRAINDICATIONS

Metronidazole is contraindicated in patients with a history of hypersensitivity to metronidazole or other nitroimidazole derivatives or any of the excipients. Metronidazole should not be administered to patients with active neurological disorders, a history of blood dyscrasia, hypothyroidism or hypoadrenalism.

DRUG INTERACTIONS

Psychotic reactions have been reported in alcoholic patients who are using metronidazole and disulfiram concurrently. Metronidazole should not be given to patients who have taken disulfiram within the last two weeks. Metronidazole has been reported to increase plasma concentrations of busulfan, which can result in an increased risk for serious busulfan toxicity. Metronidazole should not be administered concomitantly with alcohol or alcohol-containing beverages, barbiturates, carbamazepine, cimetidine, fluorouracil, lithium, methadone, phenytoin, and warfarin. Metronidazole may interfere with certain types of determinations of serum chemistry values, such as aspartate aminotransferase (AST or SGOT), alanine aminotransferase (ALT or SGPT), and lactate dehydrogenase (LDH), triglycerides, and glucose hexokinase.

PRECAUTIONS

Metronidazole should be used with caution in patients with following conditions- active or chronic severe peripheral and central nervous system, hepatic encephalopathy and ' anaemia or other blood disorders.

WARNINGS

Patients should be warned that metronidazole may darken urine (due to metronidazole metabolite). Patients should be warned about the potential for confusion, dizziness, hallucinations, convulsions or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur.

OVERDOSE

Symptoms were limited to vomiting, ataxia and slight disorientation. Single oral doses of metronidazole up to 12g have been reported in suicide attempts and accidental overdose. Management of overdose:There is no specific antidote for metronidazole over dosages. In case of suspected massive over dosages, a symptomatic and supportive treatment should be instituted.

PHARMACEUTICAL PRECAUTION

Keep away from the reach of children. Store in a cool (below 25°C) & dry place protected from light.

Special precautions for disposal and other handling

- Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.
- Do not remove 'Flip off seal' until ready for use. The product should be used immediately after opening.
- Do not use containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
- The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
- Discard after single use.
- Discard any unused portion.
- Do not reconnect partially used bottles.

PRESENTATION

Each 100 ml BIOZYL IV contains Metronidazole BP 500 mg (5 mg/ml) for intravenous infusion.

PACKAGE QUANTITY

BIOZYL IV is available in 100 ml glass vial.

Manufactured by
Popular Pharmaceuticals Ltd for
BIOPHARMA
LIMITED
A-116, BSCIC Industrial Estate,
TONGI, GAZIPUR, BANGLADESH