Package Leaflet : Information for the Patient

Rx Metronidazole Injection IP (500mg/100ml)

AMERICAN
INFECGYL IV
Infusion

Composition :
Each 100 ml Contains :
Metronidazole IP 500 mg
Water For Injections IP q.s.

Form & presentation
Solution for intravenous infusion. Vial of 100 ml solution.

Composition
1 Vial of 100 ml infusion solution contains 500 mg of Metronidazole.

Pharmacotherapeutic class
Anti-bacterial/imidazole derivatives (J: General anti-infective)

Therapeutic indications
This drug is indicated in the treatment of amoebiasis and infections involving sensitive anaerobic micro-organisms.

Dosage
Strictly follow the recommended dosage unless directed otherwise by the physician. Amoebiasis
Adults: 1.5 g/day by 2 or 3 intravenous infusions
Children: 30 to 40 mg/kg/day by 2 or 3 intravenous infusions
Anaerobic infections
Adults: 1g to 1.5g/day by 2 or 3 intravenous infusions
Children: 20 to 30 mg/kg/day by 2 or 3 intravenous infusions.

Method of administration
Metronidazole Injection should be administered by intravenous infusion over a period of 30 to 60 minutes. Slow infusion into a large vein will minimize patient discomfort and reduce the risk of venous irritation. The infusion solution can be infused either directly or after mixing with other compatible infusion solutions.

Contraindications
Metronidazole Injection is contraindicated in patients with known 'hypersensitivity (allergy) to metronidazole or to other drugs containing imidazole derivatives.

Warnings and precautions
If for compelling reasons, metronidazole must be administered longer than the usually recommended duration, it is recommended that hematological tests, especially white blood cell count should be carried out regularly and that patients should be monitored for adverse reactions, such as peripheral or central neuropathy (such as paresthesia, ataxia, dizziness, convulsive seizures). Patients should be advised not to drink alcohol during treatment and for at least 24 hours following the end of the treatment due to the possibility of a disulfiram like reaction (e.g.: redness, flushing, vomiting and fast heart rate).
Metronidazole Injection should be used with caution with active or chronic severe peripheral and central nervous system diseases due to the risk of neurological aggravation.
Reddish brown coloration of the urine, without any consequence, may occur during the treatment. Metronidazole Injection should be administered with caution to patients with hepatic encephalopathy.

Drivers and machinery operators
Due to the risk of confusion, dizziness, hallucinations, convulsions or transient visual disorders associated with the use of this drug, patients should be advised not to drive or operate machinery if these symptoms occur.

Interactions
In order to avoid possible interactions with other medicines, inform your physician or pharmacist about any other current treatment. Metronidazole Injection should not be used in association with disulfiram, alcohol and drugs containing alcohol. Metronidazole Injection may also interact with the following drugs oral anticoagulants therapy (monitor prothrombin time and adjust anticoagulant therapy as needed due to increased bleeding potential), lithium and cyclosporine (monitor levels as it may be increased), phenytoin and phenobarbital (decreased level of metronidazole), 5-Fluorouracil (monitor for signs of toxicity as the clearance may be reduced).

Pregnancy and lactation
As Metronidazole Injection crosses the placental barrier, its use in pregnancy should be carefully evaluated. As Metronidazole Injection is excreted in breast milk this drug is not recommended during lactation.

Undesirable effects
Please tell your physician or pharmacist, if you experience any adverse effect with the use of this product.

The following undesirable effects may occur:
Digestive troubles: abdominal cramp, nausea, vomiting, diarrhea, oral mucositis (inflammation of the oral mucous membrane), taste impairment, loss of appetite, exceptional and reversible cases of pancreatitis (inflammation of the pancreas), Allergic reactions rash (eruption), pruritus (itching), flushing, urticaria (skin eruption with itching wheals), fever and angioedema (severe condition characterized by the swelling of face, tongue, throat or larynx), exceptional anaphylactic shocks (severe allergic reaction of sudden onset), and very rare pustular eruptions,Peripheral and central nervous system disorders: peripheral sensory neuropathy, headache, dizziness, convulsions and ataxia (incoordination of voluntary movements), Psychiatric disorders: psychotic disorders with confusion and hallucinations.

Vision disorders:
transient vision disorders such as diplopia (perception of double vision) or myopia,

Hematology disorders: very rare cases of agranulocytosis (decrease in blood count of certain white cells), neutropenia (decrease in the number of neutrophils, a type of white blood cells) and thrombocytopenia (decrease of the number of platelets) have been reported.

Liver: very rare cases of abnormality on the test of hepatic function and reversible cholestatic hepatitis.

Overdosage
There is no specific antidote. In case of over dosage, a symptomatic treatment should be instituted.

Dosage : As directed by the Physician.
Storage : Store at a temperature not exceeding 30°C.
Do not freeze. Protect from light.
Keep the medicine out of reach of children.

Do not uses after the expiry date.

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