For the use of a Registered Medical Practitioner Only

ORNIGYL® IV

℞ Ornidazole Injection (0.5% w/v)

COMPOSITION

Each 100ml contains:

Ornidazole IP …….....500 mg

Sodium Chloride IP…….0.6083% w/v

Water for Injection IP……..... q.s.

DOSAGE FORM

Solution for Infusion

THERAPEUTIC INDICATIONS

Ornidazole IV is indicated in the treatment of susceptible protozoal infections and anaerobic bacterial infections only.

POSOLOGY AND METHOD OF ADMINISTRATION

The drug is administered intravenously during 15-30 minutes.

The solution is to be inspected visually for particulate matter and discolouration prior to administration and should only be used if it is clear and free from particles.

In cases of anaerobic infections in adults and children over 12: a first dose of 500-1000 mg is administered, followed by 500 mg doses at 12-hour intervals, or 1000 mg doses at 24-hour intervals, during 5-10 days (sequential dose). After the patient's state has been stabilized, Ornidazole should be administered orally (e.g. one 500 mg tablet at 12-hour intervals).

The daily dose for children under 12 with body mass over 6 kg is calculated as 20 mg/kg of body weight, divided into 2 doses, during 5-10 days.

For prophylaxis of anaerobic infections in adults and children over 12: 500-1000 mg of Ornidazole is administered intravenously thirty minutes before surgery.

For prophylaxis of poly-infections: Ornidazole should be used concurrently with aminoglycosides, penicillin or cephalosporins. The drugs should be administered separately.

Severe intestinal ameobiasis, all extra-intestinal ameobiasis forms.

In adults and children over 12: a first dose of 500-1000 mg is administered, followed by 500 mg doses at 12-hour intervals during 3-6 days.

In children under 12 years of age: the dose of Ornidazole is calculated as 20-30 mg/kg of body mass, divided into 2 doses.

In patients with impaired renal function, the interval between the doses should be increased, or the single and daily doses of the drug decreased.

CONTRA-INDICATIONS

Hypersensitivity to any of the drug components;

Organic central nervous system diseases;

Epilepsy, disseminated sclerosis;

Circulation disorders;

Chronic alcoholism;

First pregnancy trimester and lactation;

Body mass under 6 kg.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Caution must be exercised if the drug is prescribed in patients with hepatic function insufficiency (dose must be decreased), brain damage, hematopoiesis disorders (high risk of leucopenia or neutropenia), and patients who abuse alcohol.

DRUG INTERACTIONS

Ornidazole potentiates the effect of the coumarin range oral anticoagulants, which requires appropriate adjustment of the dose of the latter. Ornidazole prolongs the myorelaxing effect of vecuronium bromide. The drug's concentration is lowered in case of concurrent administration of microsomal enzyme inducers (phenobarbital, rifampicin) and increases in case of concurrent administration of liver microsomal system inhibitors, particularly H2-receptor blockers (cimetidine).

Isolated cases of peripheral nephritis, psychic depression and epilepsy-like convulsions were reported in cases of concurrent use of other 5-nitroimidazole derivatives.

USE IN SPECIAL POPULATIONS

Pregnancy & Lactation:

Ornidazole is contraindicated during the first pregnancy trimester. In the second and third trimesters the drug is prescribed only by absolute indications.

Lactation: If therapy by Ornidazole becomes necessary during lactation, breastfeeding must be stopped.

Paediatrics:

No data on contraindications for administration in children under 1 year of age, if the body mass of the child exceeds 6 kg.

UNDESIRABLE EFFECTS

Digestive system disorders: metal aftertaste, dry mouth, coated tongue, nausea, loss of appetite, stomach pain, diarrhea, vomiting, altered liver function test results.

Nervous system disorders: headache, vertigo, tremor, muscle rigidity, movement coordination disorders, ataxia, convulsions, confused consciousness, signs of sensory or mixed peripheral neuropathy.

Allergic reactions: very rarely – angioneurotic edema; skin rash, itching, nettle rash.

Other disorders: moderate leucopenia, darkened urine color, cardiovascular disorders.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Kindly report any suspected adverse reactions to pharmavigil@jbcpl.com

OVERDOSE

Symptoms: loss of consciousness, headache, vertigo, trembling, convulsions, depression, peripheral nephritis, nausea, vomiting.

Treatment: symptomatic treatment, specific antidote unknown.

CLINICAL PHARMACOLOGY

Pharmacodynamic properties:

Pharmacotherapeutic group: Antibacterial drugs for systemic use.

Imidazole derivatives. Ornidazole.

Ornidazole is a derivative antibiotic substance of 5-nitroimidazole. It has an antibacterial effect similar to that of metronidazole and other 5-nitroimidazoles. Effective against *Trichomonas vaginalis, Entamoeba histolytica, Giardia lamblia* (Giardia intestinalis), as well as some anaerobic bacteria, such as *Gardnerella vaginalis, Bacteroides* and *Clostridium spp., Fusobacterium* and *anaerobic cocci.* Has an antiprotosoa effect against *Balantidium coli*, *Bastocytis hominis, Trichomonas vaginalis, Trichonomus foetus, Giardia intestinalis* and *Entamoeba histolytica.*

In terms of the mechanism of action, Ornidazole is a DNA-tropic drug with selective activity against microorganisms with enzyme systems capable of reducing the nitrogroup and catalyze the interaction between ferrodoxin proteins and nitrocompounds. After the drug penetrates the microbial cell, the mechanism of its action is based reducing the nitrogroup under the influence of the microorganism's nitroreductases and the activity of the reduced nitroimidazole. The reduction products create compounds with DNA causing it to degrade, and disrupt the DNA replication and transcription processes. Furthermore, the drug's metabolism products have cytotoxic properties and disrupt cellular respiration processes.

Pharmacokinetics properties:

After intravenous drop infusion of the first dose of 15 mg/hour and subsequent administration of 7.5 mg/kg of body mass at 6-hour intervals, the maximum steady concentration is 26 μg/ml, while the minimum steady concentration is 18 μg/ml. Ornidazole is distributed throughout many tissues and body fluids, such as bile, saliva, pleural, peritoneal and cerebrospinal fluid (approximately 43% of the blood plasma concentration), vaginal secretion, bone tissue, liver, erythrocytes. Binding with plasma proteins is under 20%. Ornidazole penetrates the placental barrier and enters breast milk. Almost 30-60% of the drug is metabolized in the body through hydroxylation, oxidation and glycosilation. The main metabolite (2-oxymetronidazole) also has an antiprotosoa and antibacterial effect. Ornidazole is mainly eliminated with the urine (60-80%), partially with bile, unchanged and as metabolites, during 5 days after a single dose.

DESCRIPTION

Ornidazole is an antibiotic used to treat protozoan infections. Its chemical formula is C7H10ClN3O3.

INCOMPATIBILITIES

The solution must not be mixed with other drugs.

STORAGE AND HANDLING INSTRUCTIONS:

Store in a cool dark place until ready for use. Do not freeze.

Keep out of reach of children.

PACKAGING INFORMATION:

100 ml bottle.

Manufactured in India by :
J. B. CHEMICALS & PHARMACEUTICALS LTD.
At: Plot No. 4, Phase IV, GIDC Industrial Area,
Panoli: 394 116, Dist. Bharuch

DATE OF REVISION
October 2021

Note: This prescribing information is applicable for India Market only.