131/12623467/1117

Directions for use
Read carefully!

Diazole Intravenous Infusion
Metronidazole BP Intravenous Infusion 500 mg

ڈائیازول

برائے انٹراوینس انفیوژن

میٹرونیڈازول ۵۰۰ ملی گرام

Composition
100 ml solution contain:
Metronidazole BP 500 mg
in phosphate-buffered isotonic solution

Pharmaco-therapeutic group
Anti-infective drug

Indications
Treatment and prophylaxis of infections that are or may be due to anaerobic bacteria.
The treatment is effective in cases of:
- infections of the central nervous system (e.g. brain abscess, meningitis);
- infections in the ear-nose-throat region (e.g. PLAUT-VINCENT-angina);
- infections of lungs and pleura (e.g. necrotising pneumonia, aspiration pneumonia, lung abscess);
- endocarditis;
- infections in the G.I. tract and the abdominal area, e.g. peritonitis, liver abscess, postoperative infections after colonic and rectal surgery, purulent diseases in the abdominal and pelvic cavities;
- gynaecological infections (e.g. endometritis, after hysterectomy or caesarean section, childbed fever, septic abortion);
- bone and joint infections (e.g. osteomyelitis);
- gas gangrene;
- septicaemia with thrombophlebitis.

A prophylactic use is always indicated prior to operations with a high risk of anaerobic infections (gynaecological and intra-abdominal operations)

Contraindications
In cases of hypersensitivity to metronidazole or other nitroimidazole derivatives (which are, however, very rare), Metronidazole Intravenous Infusion 500 mg should only be given for life-threatening infections when other antibiotic treatment is ineffective.

Precautions for use
In situations of severe liver damage, impaired haematopoiesis (e.g. granulocytopenia) or diseases of the central or peripheral nervous system Metronidazole Intravenous Infusion 500 mg should only be given if its expected benefits clearly outweigh potential hazards.

Metronidazole interferes with the spectrophotometric determination of SGOT resulting in decreased values.

Pregnancy and lactation
Although there are no conclusive data indicating that metronidazole could be embryo- or fetotoxic, Metronidazole Intravenous Infusion 500 mg should only be given for life-threatening infections during pregnancy and the lactation period.

Since metronidazole is secreted into breastmilk, nursing is to be interrupted during therapy. After cessation of therapy with metronidazole, nursing should not be resumed before another 2 - 3 days because of the prolonged serum half-life time of metronidazole.

Interactions
Metronidazole / alcohol
Intake of alcoholic beverages must be avoided during metronidazole therapy since adverse reactions such as dizziness and vomiting may be the consequence (disulfiram-like effect). Simultaneous administration of disulfiram may cause states of confusion.

Metronidazole / anticoagulants
Metronidazole may affect the serum concentration of anticoagulants. In patients receiving such medicaments the anticoagulant dosage regimen must be re-adjusted, if necessary, because metronidazole has a synergetic effect on anticoagulant drugs.

Metronidazole / lithium
Caution is to be exercised when metronidazole is administered simultaneously with lithium salts, because under metronidazole therapy raised serum concentrations of lithium have been observed.

Metronidazole / anticonvulsive drugs
The efficacy of metronidazole is reduced when barbiturates or phenytoin are administered simultaneously.

Metronidazole / cimetidine
Concurrently administered cimetidine may reduce the elimination of metronidazole in isolated cases and subsequently lead to increased metronidazole concentrations in the serum.

Special warnings
Effects on ability to drive and to use machines:
Even when used as directed, metronidazole may alter reactivity so far that the ability to drive or to use machinery is impaired. This holds true to a still higher degree at the beginning of treatment or in combination with alcohol intake.

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Dosage

The following dosage guidelines should be followed:

Adults and children over 12 years
On the 1st day of therapy, every 6 - 8 hours 500 mg of metronidazole (corresponding to 100 ml of Metronidazole Intravenous Infusion 500 mg), up to max 2.0 g per day.

On the 2nd and the following days, every 12 hours 500 mg of metronidazole, i. e. 1.0 g of metronidazole per day. Only exceptionally, if clearly indicated, the maintenance dose may be increased to 1.5 g per day.

As a rule, the treatment period is 5 to 7 days (see also "Duration of therapy" below).

For preoperative prophylaxis of infection a single dose of 0.5 - 1.0 (2.0 g max.) of metronidazole should be given immediately prior to the beginning of the operation.

Children under 12 years
Every 8 hours 7 - 10 mg of metronidazole per kg B.W., corresponding to a daily dose of 20 - 30 mg of metronidazole per kg b.w.

Duration of therapy:
The duration of therapy with metronidazole or drugs containing other nitroimidazoles should not exceed 10 days. Only in individual cases and if clearly needed, the treatment period may be extended.

Repeat therapy should be restricted as much as possible and to specific elective cases only. This limitation must be observed strictly because the possibility of metronidazole developing mutagenic activity cannot be safely excluded and because in animal experiments an increase of the incidence of certain tumours has been noted.

Method of administration

Intravenous infusion.

The contents of one bottle are to be infused slowly i.v., i. e. 100 ml max. over not less than 20 minutes, but normally over one hour.

Metronidazole Intravenous Infusion 500 mg can also be diluted before administration, adding the drug to an i.v. vehicle solution such as 0.9% Sodium Chloride or 5% Glucose Infusion Solution.

Simultaneously prescribed antibiotics are to be administered separately.

Overdose

There is no specific treatment for gross overdose of metronidazole. If required, metronidazole can be effectively eliminated by haemodialysis.

Undesirable effects

Effects on the gastro-intestinal tract
Occasionally, metallic taste, eructation with bitter taste, furry tongue, glossitis and stomatitis, epigastric pressure, nausea, vomiting, loss of appetite, and diarrhoea may occur.

In very rare cases of severe persistent diarrhoea during and after therapy the attending doctor should be informed, because those symptoms may be caused by pseudomembraneous colitis, which requires immediate treatment. In those cases administration of Metronidazole Intravenous Infusion 500 mg is to be discontinued and appropriate therapy (e. g. vancomycin, orally 4 times 250 mg per day) must be instituted. Peristalsis inhibiting drugs are contraindicated.

Effects on liver and pancreas
Rarely, disorders of liver function (e. g. raised serum levels of transaminases and bilirubin) may occur; sporadically: pancreatitis.

Symptoms of hypersensitivity
Occasionally, skin affections (e. g. pruritus, urticaria) and drug fever may appear.
Severe acute hypersensitivity reactions (i. e. anaphylactic reactions, up to anaphylactic shock) may occur, but these are very rare. Such reactions necessitate immediate therapeutic intervention.

Effects on central and peripheral nervous system
Occasionally, headache, vertigo, somnolence or insomnia, states of confusion, irritability, depression, and ataxia may be observed.
Also occasionally, during administration of Metronidazole Intravenous Infusion 500 mg, peripheral nervous disorders (neuropathia) and seizures have been observed. The former become manifest as paraesthesia, furry sensation, and tingling in the extremities. In such cases the attending doctor should be informed immediately.

Effects on blood and blood cell counts
During therapy with Metronidazole Intravenous Infusion 500 mg, decreases of leukocyte and platelet counts (leukopenia, granulocytopenia, in isolated cases even up to agranulocytosis, and thrombocytopenia) have been seen occasionally. Therefore, under prolonged administration regular monitoring of the blood cell counts is mandatory.

Effects on kidneys and bladder
Dysuria, cystitis, and urinary incontinence are very rare occurrences.

Other effects
Occasionally, darkened urine (due to a metabolite of metronidazole) may be observed; rare side effects are genital superinfections with candida, weakness, and blurred vision.

Local reactions
After intravenous administration, vein irritations (up to thrombophlebitis) may occur.

Storage

The product should not be stored above the temperature stated on the label. Protect from light.

Expiry date

Do not use the product beyond the expiry date stated on the label.

Presentation

100 ml plastic container.

احتیاطی تدابیر:
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
دوا کو 30°C سے کم درجہ حرارت پر رکھیں۔

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