Cipronat® IV

ciprofloxacine

FAST AND EFFICIENT IN CASE OF AN EMERGENCY

Bactericidal fluorochinolone 200 mg IV

200 mg, 2 to 3 times a day, by IV infusion
May be increased to 400 mg, 2 to 3 times per day

Bactericidal activity against the majority of gram-positive and gram-negative pathogens

DAFRA PHARMA INTERNATIONAL

Headquarters
Slachthuisstraat 30/7
2300 Turnhout
Belgium

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Dafra PHARMA

Setting the Standard

www.dafrapharma.com

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EUROPEAN GMP

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REASSURING SPECTRUM OF ACTION

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PRESENTATION

CIPRONAT® solution for I.V. infusion is supplied in the form of a transparent glass vial containing 100 ml of sterile aqueous solution corresponding to 200 mg of ciprofloxacin.

INDICATIONS

CIPRONAT®IV is indicated in the treatment of infections due to pathogens sensitive to ciprofloxacin:

- Infections of the airways and of the ENT region, particularly those due to Gram-negative pathogens.
- Infections of the mouth, teeth and jaws.
- Infections of the kidneys and/or the urinary tract.
- Genital infections, including gonorrhoea and adnexitis.
- Infections of the gastrointestinal tract.
- Infections of the bile ducts.
- Infections of wounds or soft tissues.
- Bone or joint infections.
- Gynaecological and obstetric infections.
- Septicaemia.
- Peritonitis.
- Eye infections.
- Typhoid fever.
- Infections or risk of infection (prophylaxis) in immunodeficient patients.

DOSAGE

The recommended dosage is 200 mg 2 to 3 times per day as an I.V. infusion. It may be increased to 400 mg 2 to 3 times per day according to the severity of the infection, particularly in the case of life-threatening infections (nosocomial pneumopathy, septicaemia, etc.)

Duration of treatment

The duration of the treatment depends on the severity of the situation as well as the clinical and bacteriological course.

In principle, the treatment should be continued consistently at least 3 days after a decrease in temperature or the disappearance of clinical symptoms.

CONTRAINDICATIONS

- Hypersensitivity to ciprofloxacin, to other quinolones or one of the excipients.
- Pregnancy and breastfeeding.
- Children under the age of 5 years.
- Children and adolescents (aged 5 to 17 years) except for infections due to Pseudomonas aeruginosa and in cases of cystic fibrosis.

A risk of joint cartilage lesions cannot be excluded in the not-yet-adult organism.

WARNINGS AND PRECAUTIONS

- Ciprofloxacin may trigger photosensitivity reactions in rare situations; such patients should avoid excessive exposure to sunlight while they are receiving treatment.
- Intravenous administration should take place in the form of an infusion over a 60-minute

period. Local reactions may appear if the duration of the infusion is 30 minutes or if small veins on the back of the hand are used.
- Long-term and repeated use may cause super-infections via resistant bacteria or yeasts.
- Since ciprofloxacin is eliminated essentially via the urine and less so via the hepatobiliary system, caution is advised in patients with renal failure.
- Crystalluriahas been reported (rarely) and therefore patients should be instructed to drink sufficient amounts of fluid.

INTERACTIONS

Ciprofloxacin is a moderate inhibitor of the 1A2 enzymes of cytochrome P450. Caution is required in the case of concomitant administration of drugs which are metabolized via the same enzymes: theophylline, methylxanthine, caffeine, tizanidine, duloxetine or clozapine.

FREQUENT ADVERSE EFFECTS

Nausea, diarrhoea, gastrointestinal problems, lack of appetite. In general, these effects disappear spontaneously when treatment is stopped.

MECHANISM OF ACTION AND PHARMACODYNAMICS

CIPRONAT® IV is an antibiotic of the quinolone group, active on a broad spectrum of Gram-positive and Gram-negative bacteria. The mechanism of action is based on the inhibition of the topoisomerase II (DNA gyrase) enzyme of the bacteria. Thus the reproductive capacity of the bacterium is rapidly decreased. The effect of ciprofloxacin is bactericidal.

PHARMACOKINETICS

Absorption

The serum concentration peaks were reached at the end of the infusion (1.8 mg/l after an infusion of 100 mg over 30 min.; 3.4 mg/l after an infusion of 200 mg over 30 min.; 3.9 mg/l after an infusion of 400 mg over 60 min.). The pharmacokinetics has proven to be linear.

Distribution

The concentrations of ciprofloxacin at the sites of infection are greater than those in the serum. The distribution volume of ciprofloxacin is 2-3 l/kg. Plasma protein binding is low (20-30%). Only small amounts of ciprofloxacin (6-10%) diffuse into cerebrospinal fluid.

Metabolism/elimination

The mean serum half-life is about 4 hours. After an intravenous infusion, 71% of the dose administered is eliminated via the urine and 17.8% via the faeces.

STORAGE

Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.
Do not store in the refrigerator.

For the complete SMPC, please visit www.dafrapharma.com