

**PATIENT INFORMATION LEAFLET  
(PIL)**

**PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER  
HABCIP (Ciprofloxacin Injection USP 200mg/100ml)**

**Strength:**

Each 100ml contains:

Ciprofloxacin USP.....200 mg  
Sodium Chloride USP.....0.9% w/v  
Lactic Acid.....64 mg  
Water for Injection USP.....q.s.

**Pharmaceutical form:** Solution for Intravenous Infusion

**Active Pharmaceutical Ingredient:** Ciprofloxacin USP

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

**In this leaflet:**

1. What Ciprofloxacin Injection USP 200mg/100ml is and what it is used for
2. Before you use Ciprofloxacin Injection USP 200mg/100ml
3. How to use Ciprofloxacin Injection USP 200mg/100ml
4. Possible side effects
5. How to store Ciprofloxacin Injection USP 200mg/100ml
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**1. WHAT COMPOUND CIPROFLOXACIN INJECTION USP 200MG/100ML IS AND WHAT IT IS USED FOR**

Ciprofloxacin 2 mg/ml solution for infusion is indicated for the treatment of the following infections. Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy.

Adults

- Lower respiratory tract infections due to Gram-negative bacteria
  - exacerbations of chronic obstructive pulmonary disease
  - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
  - pneumonia
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
- Acute pyelonephritis
- Bacterial prostatitis
- Genital tract infections
  - epididymo-orchitis including cases due to susceptible *Neisseria gonorrhoeae*
  - pelvic inflammatory disease including cases due to susceptible *Neisseria gonorrhoeae*

- Infections of the gastro-intestinal tract (e.g. travellers` diarrhoea)
- Intra-abdominal infections
- Complicated skin and skin structure infections/complicated skin and soft tissue infections
- Malignant external otitis
- Infections of the bones and joints
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Children and adolescents

- Broncho-pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis
- Complicated urinary tract infections and acute pyelonephritis
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered to be necessary.

Treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

## 2. BEFORE YOU ARE GIVEN CIPROFLOXACIN INJECTION USP 200MG/100ML

### **Do not use**

if you are allergic to the active substance, to other quinolone drugs or to any of the other ingredients of this medicine

- if you are taking tizanidine

### **Warnings and precautions:**

#### **Before you use Ciprofloxacin Injection USP 200mg/100ml**

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Ciprofloxacin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible

#### **Taking or using other medicines:**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is preferable to avoid the use of Ciprofloxacin during pregnancy. Do not take Ciprofloxacin during breast-feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

#### **Driving and using machines**

Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive or to operate machinery may be impaired.

## 3. HOW TO USE CIPROFLOXACIN INJECTION USP 200MG/100ML

Your doctor will explain to you exactly how much Ciprofloxacin you will be given as well as how often and for how long. This will depend on the type of infection you have and how bad it is.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

Treatment usually lasts between 5 and 21 days, but may be longer for severe infections.

Your doctor will give you each dose by slow infusion through a vein into your bloodstream. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60

minutes for 400 mg Ciprofloxacin and 30 minutes for 200 mg Ciprofloxacin. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are taking this medicine.

If you stop your course of Ciprofloxacin, it is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop using this medicine too soon your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antibiotic.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following section contains the most serious side effects that you can recognise yourself: Stop taking Ciprofloxacin and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

##### **Uncommon (may affect up to 1 in 100 people)**

- seizure

##### **Rare (may affect up to 1 in 1,000 people)**

- severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic shock)
- tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon)

##### **Very rare (may affect up to 1 in 10,000 people)**

- severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction)
- muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon)
- unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy)
- a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis).

Other side effects which have been observed during treatment with Ciprofloxacin are listed below by how likely they are:

##### **Common (may affect up to 1 in 10 people)**

- nausea, diarrhoea, vomiting • joint pain and joint inflammation in children
- local reaction at the injection site, rash
- temporary increased amounts of substances in the blood (transaminases)

##### **Uncommon (may affect up to 1 in 100 people)**

- joint pain in adults • fungal superinfections
- a high concentration of eosinophils, a type of white blood cell, increased or decreased amounts of a blood clotting factor (thrombocytes)
- decreased appetite • hyperactivity, agitation, confusion, disorientation, hallucinations

- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses, giddiness • eyesight problems including double vision
- loss of hearing
- rapid heartbeat (tachycardia)

**Rare (may affect up to 1 in 1,000 people)**

- muscle pain, inflammation of the joints, increased muscle tone and cramping • inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angiooedema)
  - increased blood sugar (hyperglycaemia)
  - decreased blood sugar (hypoglycaemia)

**Very rare (may affect up to 1 in 10,000 people)**

- A special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis)
- Allergic reaction called serum sickness-like reaction
  - Disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri) • visual colour distortions
- Various skin eruptions or rashes • worsening of the symptoms of myasthenia gravis
- fatigue
- Memory impairment

**5. HOW TO STORE CIPROFLOXACIN INJECTION USP 200MG/100ML**

Store below 30°C. Protect from light. Do not refrigerate or freeze.

**6. FURTHER INFORMATION**

**What Ciprofloxacin Injection USP 200mg/100ml contains**

Active ingredient is Ciprofloxacin USP. Also contains Lactic Acid, Disodium Edetate, Sodium chloride, Sodium Hydroxide, Hydrochloric acid, Water for injection.

**What Ciprofloxacin Injection USP 200mg/100ml looks like and contents of the pack**

100 ml LDPE bottle with Dust cap/Euro Head cap, with pre-printed label packed in a Unit Carton, along with the pack insert.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

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