

# CIPROFLO INFO 2 MG/ML CIPROFLOXACIN

## COMPOSITION

SubActive substance : Ciprofloxacin ..... 200 mg  
Excipients: Glucose monohydrate – Lactic acid – Hydrochloric acid – WFI.....QS 100 ml

## PHARMACEUTICAL FORM & PRESENTATION

Injectable solution for infusion, flexible sterile PVC bag with metallic overwrap  
• Box of 30 bags of 200 ml  
• Box of 50 bags of 100 ml

## INDICATIONS

This drug is an antibacterial antibiotic of the quinolone class, it is a fluoroquinolone. Ciprofloxacin acts by killing bacteria that cause infections. It is active only on specific strains of bacteria.

**In the Adult**  
CIPROFLO INFO is used in adults to treat the following bacterial infections:

- respiratory infections
- persistent or recurrent infection of ear or sinuses
- urinary infections
- infections of the testicles
- genital infections in women
- gastro-intestinal infections and intra-abdominal infections
- infections of skin and of soft tissue
- infections of bones and articulations
- exposure to anthrax

If the patient has serious infections or an infection caused by different types of bacteria, an additional antibiotic treatment may be prescribed as a complement to CIPROFLO INFO. **In children and teenagers** CIPROFLO INFO is used in children and teenagers, under the control of a specialist, to treat the following bacterial infections:

- infections of the lungs and bronchi in children and teenagers with mucoviscidosis
- exposure to anthrax

CIPROFLO INFO may be also used to treat others specific serious infections in children and teenagers if the doctor deems necessary.

## CONTRAINDICATIONS

**Never to take CIPROFLO INFO 2 mg / ml, bag of solution for infusion:**

- in case of allergy (hypersensitivity) to the active substance, to others quinolones or to any of the other ingredients of CIPROFLO INFO 2mg/ml, bag of solution for infusion (see paragraph "Composition");
- in case of treatment with tizanidine (see paragraph "Interactions").

## WARNINGS & PRECAUTIONS OF USE

Be careful with CIPROFLO INFO 2 mg / ml solution for infusion bag

Before receiving CIPROFLO INFO 2 mg / ml solution for infusion bag

The doctor should be informed when:

- history of kidney problems, because it may be necessary to adapt treatment
- epilepsy or other neurological disease
- history of the tendon problems with antibiotics from the same family as ciprofloxacin
- of myasthenia (a rare disease that causes muscular weakness)
- history of abnormal heart rhythm (arrhythmia).

During treatment with CIPROFLO INFO 2 mg / ml, solution for infusion bag, the doctor should be warned

immediately if any of the following conditions occurs to decide or not the interruption of treatment :

- **Sudden and serious allergic reaction** (reaction/allergic shock, angioneurotic edema). After the first dose, there is a low risk of the occurrence a serious allergic reaction, manifested by the following symptoms:

tightness in the chest, giddiness, sickness or fainting, or giddiness when getting up from a standing position.

If these symptoms occur, treatment with CIPROFLO INFO should be stopped, because the patient's life could be in danger.

- Pains and swellings of articulations and tendonitis may occasionally occurs, particular in the case of elderly and corticosteroid treatment. At any sign of pain or inflammation of the articulations or tendons, the treatment with CIPROFLO INFO should be stopped, then put the limb affected at rest. Avoid useless effort because it may increase the risks of tendon rupture.

In case of epilepsy or other neurological disease cerebral type ischemia or cerebrovascular accident, neurological, neurological undesirable effects (convulsive seizures) may occur. If they occur, treatment with CIPROFLO INFO should be stopped.

Psychiatric reactions may occur after the first dose of CIPROFLO INFO. In case of depression or psychosis, the symptoms may worsen during treatment with CIPROFLO INFO. In these cases, the treatment with CIPROFLO INFO must be stopped

Evocative neuropathy symptoms may occur, such as pain, burning, tingling, numbness and / or muscle weakness. If such symptoms occur, the treatment with CIPROFLO INFO should be stopped.

Diarrhea may occur during the taking of antibiotics, including CIPROFLO INFO, even many weeks after completion of treatment. If diarrhea is serious or persists or if we notice the presence of blood or mucus in the stool. CIPROFLO INFO treatment should be stopped immediately because the patient's life could be in danger. Do not take medicaments intended to block or slow intestinal transit.

The doctor or the analysis laboratory should be warned by taking CIPROFLO INFO in case of sampling of blood or urine.

CIPROFLO INFO can cause hepatic problems. The doctor should be notified by the slightest symptom of such loss of appetite, jaundice, dark urine, itching or stomach sensitivity on palpation, treatment with CIPROFLO INFO should be stopped.

CIPROFLO INFO can decrease the rate of white cells in the blood and reduce resistance to infections.

If a patient presents an infection with symptoms such as fever, and serious deterioration of his general condition, or fever with local infection symptoms such as pain in the throat / pharynx / mouth or the urinary problems, he should consult the doctor immediately. The blood analysis will be carried to search an eventual reduction in the rates of certain white cells (agranulocytosis).

The doctor should be warned if the patient or a family member is suffering from glucose-6-phosphate dehydrogenase deficiency (G6PD), a risk of developing anemia with ciprofloxacin is likely.

• Avoid any prolonged exposure to sunlight or artificial UV rays.

## DRUG INTERACTIONS & OTHER FORMS OF INTERACTION

Taking or using other drugs

Don't use CIPROFLO INFO at the same time as tizanidine as this may cause adverse effects such as a decrease in blood pressure and the sleepiness (see paragraph "Contraindications").

The following drugs are known to interact with CIPROFLO INFO. Use the CIPROFLO INFO at the same time as these drugs could have an impact on the therapeutic effects of these products, and increase the probability of adverse effects.

Take into account in case of taking of any of the following drugs

- warfarin or other oral anticoagulants (to thin the blood)
  - probenecid (used to treat gout)
  - methotrexate (used in some types of cancer, psoriasis, rheumatoid arthritis)
  - theophylline (used in respiratory problems)
  - tizanidine (used in problems of muscle spasticity associated with multiple sclerosis)
  - clozapine (used in certain psychiatric diseases)
  - ropinirole (used in Parkinson's disease)
  - Phenytoin (used in epilepsy)
- CIPROFLO INFO may increase the concentration of these drugs in your blood:
- pentoxifylline (used in circulatory problems)
  - caffeine

Food and drinks do not have an effect on treatment with CIPROFLO INFO 2 mg / ml solution for infusion bag.

## PREGNANCY & BREAST-FEEDING

It is preferable to avoid using CIPROFLO INFO during pregnancy.

Don't take CIPROFLO INFO during breastfeeding because ciprofloxacin passes into breast milk and could harm the health of the child.

## DRIVING & USING MACHINES

CIPROFLO INFO can reduce the level of vigilance. Neurological undesirable effects may occur.

## EXCIPIENTS WITH KNOWN EFFECTS

This drug contains 5 g of glucose per 100 ml which must be taken account in the daily ration in the case of low-sugar diet or diabetes.

Use of this drug is not recommended in patients with malabsorption of glucose and galactose.

## POSOLGY & ADMINISTRATION MODE

The doctor will explain exactly to the patient how much CIPROFLO INFO will be given, how often and for how long. This will depend on the type of infection and its severity.

The doctor must be warned in case of kidney problems because the dose of medicine to be taken may have to be adapted. The treatment usually lasts 5 to 21 days but can be longer in case of severe infection. The healthcare professional will inject each dose into the bloodstream as a slow intravenous infusion. In children, the infusion will last 60 minutes.

In adults, the duration of the infusion will be 60 minutes for administration of the 400 mg solution of CIPROFLO INFO 2 mg/ml, bag of solution for infusion bag and 30 minutes for administration of the 200 mg solution of CIPROFLO INFO 2 mg/ml, bag of solution for infusion bag.

Administering the infusion slowly helps to prevent the occurrence of immediate side effects.

Remember to drink plenty of fluids while taking CIPROFLO INFO.

**If you stop the treatment with CIPROFLO INFO 2 mg / ml, solution for infusion bag:**

It is important that the patient monitor the treatment until the end even in case of improvement in clinical signs after a few days. In case of early stopping of treatment, the infection could not be completely cured and the symptoms of the infection could be recur or worsen. Bacterial resistance to this antibiotic may develop. The infusion solution can be injected either directly or after mixing with other compatible infusion solutions. The solution for infusion must be systematically administered separately, unless the compatibility with drugs / infusion solutions was determined. The visual signs of incompatibility are, for example, the formation of a precipitate, a turbid solution or a change of color.

An incompatibility reaction will occur with drug / any solution for infusion having a physical or chemical instability of the solution pH (for example, Penicillin or heparin solutions), in particular with the solutions adjusted to obtain a pH alkaline (pH of the ciprofloxacin infusion solution: 3.5-4.6). A treatment initiated intravenously can be continued orally.

## SIDE EFFECTS

Like all drugs, CIPROFLO INFO 2mg/ml solution for infusion bag may cause side effects, although it don't occurs systematically them in everyone.

Common side effects (between 1 and 10 people on 100 may have the following effects):

- sickness, diarrhea, vomiting
- articulation pains in children
- local reaction at the injection site, skin rash
- temporary elevation of certain liver enzymes in the blood (transaminases)

Common side effects (between 1 and 10 people on 1000 may have the following effects):

- fungal superinfection (caused by fungi)
- high concentration of eosinophils (a type of white cells), increase or decrease of these cells in the blood serving to blood coagulation (platelets)
- loss of appetite (anorexia)

- hyperactivity, agitation, confusion, disorientation, hallucinations
- headache, dizziness, sleep disturbances, taste disturbances, tingle, unusual sensitivity, seizures (see paragraph "Warnings and Precautions"), giddiness
- vision problems
- hearing loss

- rapid heartbeat (tachycardia)
- dilation of blood vessels (vasodilation), low blood pressure
- abdominal pain, digestive problems such as stomach problems (indigestion / heartburn) or flatulence
- temporary hepatic disorders, increasing the amount of a substance in the blood (bilirubin), jaundice (cholestatic jaundice)

- itching, hives
- pain in the muscles or bones, articulation pain in adults
- impaired renal function, renal failure

- general feeling of weakness (asthenia), fever, fluid retention
- increase levels of alkaline phosphatase blood (a substance in the blood)

Rare side effects (between 1 and 10 per 10 000 persons may have the following effects):

- inflammation of the intestines (colitis) linked to antibiotic use (which can be fatal in rare cases) (see paragraph "Warnings and Precautions of use")
- change in the number of red blood cells or of certain white cells (leukopenia, leukocytosis, neutropenia, anemia), simultaneous decrease of the number of red cells, white cells and platelets (pancytopenia) may be fatal, bone marrow aplasia (loss of bone marrow into blood cells) can also be fatal (see paragraph "Warnings and Precautions of use")

- allergic reaction, allergic swelling (edema) or rapid swelling of the skin and mucosa (angioedema), anaphylactic shock [abrupt swelling of the face and neck with breathing difficulties] which may be life-threatening (see paragraph "Warnings and Precautions of use")
- increase in blood sugar levels (hyperglycemia)

- reactions of anxiety, strange dreams, depression, psychiatric disorders (psychotic reactions) (see paragraph "Warnings and Precautions of use")

- decreased skin sensitivity, tremors, headache, impaired smell (olfactory disorders)

- ringing in the ears, hearing problems
- fainting, inflammation of the lining of blood vessels (vasculitis)

- shortness of breath, including asthmatic symptoms
- pancreatitis (inflammation of the pancreas)

- hepatitis, destruction of liver cells (liver necrosis) leading to hepatic failure which may be life-threatening.
- sensitivity to light (see paragraph "Warnings and Precautions of use"), slight bleeding in the form of red spots under the skin (petechiae)

- muscle pain, inflammation of articulations, increase muscle tone and cramping, tendon rupture - especially the large tendon at the back of the ankle (Achilles tendon) (see paragraph "Warnings and Precautions of use")
- presence of blood or crystals in the urine (see paragraph "Warnings and Precautions of use"), urinary tract inflammation

- excessive sweating
- concentration in the abnormal blood coagulation factor (prothrombin), increased concentration in the blood of the enzyme amylase (an enzyme from the pancreas)

Very rare side effects (less than 1 on 10 000 can have the following effects):

- decrease of the specific origin of red cells (hemolytic anemia), very significant decrease in the number of certain white cells (agranulocytosis)
- Serious allergic reactions (anaphylactic reaction, serum sickness) which may be life-threatening. (see paragraph "Warnings and Precautions of use")

- coordination disorders, unsteady gait (difficulty walking), intracranial hypertension
- disorders of color vision

- various skin rashes (for example Stevens Johnson Syndrome, or Lyell's Syndrome [skin peeling can quickly spread to the entire body] potentially fatal)
- muscle weakness, tendon inflammation, increase in symptoms of myasthenia (see paragraph "Special warnings and precautions for use")

Undetermined frequency (cannot be estimated from the basis of available data)

- neurological symptoms such as pain, burning, tingling, numbness and / or weakness in the extremities
- serious abnormal heart rhythms, irregular heartbeat.

## STORAGE

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the outer carton.

Store in the overwrap, protected from light, at a temperature not exceeding 25 ° C.

Do not put the bag in the refrigerator and do not freeze.

If the solution is kept at a low temperature, a precipitate may form which is redissolved at room temperature.

The bag should be used immediately after opening. Otherwise, the conditions and the storage time in use are the responsibility of the user.

## CONDITIONS OF ISSUE:

List I – Table A - For hospital use.

## MARKETING AUTHORISATION N°

CIPROFLO INFO 2MG/ML, Bag of 100 ml : 919 317 1H

CIPROFLO INFO 2MG/ML, Bag of 200 ml : 919 317 2H

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Manufactured by : INFOMED PHARMA

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### THIS IS A DRUG

- A drug is a product but not like the others.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Your doctor and pharmacist know about the drug, its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescribed period.
- Do not pick up, do not increase the dose without consulting your doctor.

Keep drugs out of the reach of children