

Ciprofloxacine

Veuillez lire attentivement cette notice avant d'utiliser ce médicament car elle contient des informations importantes pour vous.
• Gardez cette notice. Vous pourriez avoir besoin de la relire.
• Si vous avez d'autres questions, interrogez votre médecin, votre pharmacien
• Ce médicament vous est personnel et réservé à votre usage. Ne le donnez pas à d'autres personnes.
Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
• Ne conservez pas de médicaments et/ou dispositifs médicaux sans avis de votre pharmacien.
• Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. Voir rubrique 4.

Que contient cette notice ?

- 1. QU'EST-CE QUE CIPRO 200 mg/100 mL, solution pour perfusion (IV) et dans quels cas est-il utilisé ?
2. Quelles sont les informations à connaître avant d'utiliser CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?
3. Comment utiliser CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?
4. Quels sont les effets indésirables éventuels ?
5. Comment conserver CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?
6. Contenu de l'emballage et autres informations.
1.1. **QU'EST-CE QUE CIPRO 200 mg/100 mL, solution pour perfusion (IV) ET DANS QUELS CAS EST-IL UTILISÉ ?**
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est un antibiotique appartenant à la famille des fluorocinolones. Elle agit en tant que bactéricide. Elle agit en empêchant la synthèse active et/ou inhibant sur certains aspects biochimiques de la bactérie.
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est indiqué dans le traitement des infections suivantes, en fonction du type de bactérie responsable. Les informations disponibles sur la résistance bactérienne à la ciprofloxacine avant d'initier le traitement sont :

- Infections des voies respiratoires basses dues à des bactéries à Gram négatif ;
• exacerbations de broncho-pneumonie chronique obstructive ;
• infections broncho-pulmonaires en cas de mucoviscidose ou de bronchite ;
• Infections chroniques purulentes ;
• Exacerbations aiguës de sinusite chronique, en particulier dues à des bactéries à Gram négatif ;
• Infections de l'appareil génital ;
• orech-épidémiques, y compris les infections dues à des souches de *Neisseria gonorrhoeae* sensibles ;
• Infections gynécologiques aiguës causées par des souches de *Neisseria gonorrhoeae* sensibles ;
• infections gastro-intestinales (en cas, de diarrhée du voyageur) ;
• Infections intra-abdominales ;
• Infections de la peau et des parties molles dues à des bactéries à Gram négatif ;
• Ostéites malignes extémes ;
• Infections ostéoarticulaires.
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est utilisé pour le traitement des patients neurologiques fébriles dont l'origine bactérienne est suspectée.

- 1.2. **CONTRE-INDICATIONS**
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est contre-indiqué dans les cas suivants :
• Infections broncho-pulmonaires en cas de mucoviscidose dues à *Pseudomonas aeruginosa* ;
• Infections urinaires compliquées et pyélonéphrite ;
• Traitement par antibiotique associé avec la ciprofloxacine.
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est également utilisé pour traiter des infections sévères de l'enfant et de l'adolescent, si nécessaire. Le traitement devra être exclusivement initié par un spécialiste expérimenté dans le traitement de la fièvre de l'enfant et de l'adolescent.

2. QUELLES SONT LES INFORMATIONS À CONNAÎTRE AVANT D'UTILISER CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?

- si vous avez déjà utilisé ce médicament ;
• si vous êtes allergique à la substance active, aux autres quinolones ou à l'un des autres composants contenus dans ce médicament (particulièrement dans les cas de mucoviscidose) ;
• si vous prenez de la thiazinide (voir rubrique 2 : Autres médicaments et CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?)
Prévenez l'inflammation des articulations ou des tendons, le traitement par CIPRO 200 mg/100 mL, solution pour perfusion (IV) est contre-indiqué si :
• vous avez déjà eu des problèmes aux tendons avec des antibiotiques de la même famille que CIPRO ;
• vous êtes âgé(e) ou de plus de 60 ans ;
• si vous souffrez d'épilepsie ou d'une autre affection neurologique ;
• si vous avez déjà eu des problèmes aux tendons avec des antibiotiques de la même famille que CIPRO ;
• si vous avez des troubles cardiaques.
La ciprofloxacine doit être utilisée avec précaution si vous êtes âgé(e) ou, ou si vous avez des problèmes cardiaques (comme un infarctus du myocarde ou une arythmie) ou si vous avez des troubles de l'équilibre du cœur, si vous avez un déséquilibre électrolytique dans le sang (notamment un taux faible de potassium ou de magnésium dans le sang), si vous avez un rythme cardiaque très lent (appelé «bradycardie»), si vous avez une maladie insuffisance cardiaque, si vous avez déjà eu une crise cardiaque (infarctus du myocarde), si vous êtes une femme ou une personne âgée ou si vous prenez des médicaments pour traiter certaines anomalies de l'ECG (voir rubrique Autres médicaments et CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?).

3. COMMENT UTILISER CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?

- Prévenez l'inflammation des articulations ainsi que des tendinites peuvent survenir occasionnellement, en particulier si vous êtes âgé(e) et si vous êtes également traité(e) par des corticoïdes. Une inflammation et une rupture des tendons peuvent survenir dès les premières 48 heures de traitement et jusqu'à plusieurs mois après l'arrêt du traitement par CIPRO.
• Évitez toute exposition prolongée au soleil ou aux rayons UV artificiels comme ceux des cabines de bronzage.
• Prévenez le médicament ou le personnel du laboratoire d'analyser que vous recevez CIPRO si vous devez subir un **prélèvement** immédiat avant votre médication.
• Évitez toute exposition prolongée au soleil ou aux rayons UV artificiels comme ceux des cabines de bronzage.
• Prévenez le médicament ou le personnel du laboratoire d'analyser que vous recevez CIPRO si vous devez subir un **prélèvement** immédiat avant votre médication.

4. QUELS SONT LES EFFETS INDÉSIRABLES ÉVENTUELS ?

- **Effets indésirables fréquents** (peuvent affecter jusqu'à 1 personne sur 10)
• douleurs dans les articulations et inflammation des articulations chez l'enfant ;
• élévation temporaire de certaines enzymes du foie présentes dans le sang (transaminases).
Effets indésirables peu fréquents (peuvent affecter jusqu'à 1 personne sur 100)
• douleurs dans les articulations chez l'adulte ;
• surinfections fongiques (dus à des champignons) ;
• rupture de l'os ou d'un tendon (le plus souvent les os et tendons des épaules), augmentation ou diminution de la quantité de facteurs présents dans le sang servant à la coagulation sanguine (plaquettes) ;
• diminution de l'appétit ;
• hyperactivité, agitation, confusion, désorientation, hallucinations ;
• maux de tête, sensations vertigineuses, troubles du sommeil, troubles du goût, fourmillements, sensibilité inhabituelle aux sensations habituelles de douleur ;
• troubles de la vision, incluant une vision double ;
• perte de l'audition ;
• accélération de battements cardiaques (tachycardie) ;
• dilatation des vaisseaux sanguins (vasodilatation), baisse de la pression artérielle ;
• douleurs abdominales, problèmes digestifs tels que des problèmes d'estomac (indigestion/troubles digestifs) ;
• démangeaisons, urticaire ;
• douleurs musculaires, insuffisance rénale ;
• douleurs dans les muscles et les os, sensation de fatigue générale (asthénie), fièvre, rétention d'eau ;
• élévation du taux d'une substance présente dans le sang (phosphatases alcalines) ;
• douleurs musculaires, inflammation des articulations, augmentation du tonus musculaire et crampes ;
• inflammation des intestins (colite) liée à l'utilisation d'antibiotiques (pouvant être fatale dans de très rares cas) (voir rubrique 2 : Avertissements et précautions) ;
• modification du nombre de certains globules blancs ou des globules rouges (leucopénie, leucocytose, neutropénie, anémie) ;
• troubles de l'audition, troubles de la vision, troubles de la parole, troubles de la coordination, troubles de la marche, pression exercée sur le cerveau (hypertension intracrânienne et pseudo-tumeur cérébrale) ;
• troubles de la vision des couleurs ;
• éruptions cutanées diverses ;
• aggravation des symptômes de la myasthénie (voir rubrique 2 : Avertissements et précautions) ;
• augmentation du nombre de cellules du foie (nécrose hépatique) aboutissant très rarement à une insuffisance hépatique mortelle ;
• hépatite, destruction des cellules du foie (nécrose hépatique) aboutissant très rarement à une insuffisance hépatique mortelle ;
• sensibilité à la lumière (voir rubrique 2 : Avertissements et précautions), petits saignements sous forme de points rouges sous la peau (pétéchies) ;
• sensation de chaleur ou de cristaux dans les urines, inflammation des voies urinaires ;
• insomnie excessive ;
• troubles de la coordination dans le sang d'une enzyme issue du pancréas (amylase).
Effets indésirables très rares (peuvent affecter jusqu'à 1 personne sur 10 000)
• type rare d'anémie (la fréquence ne peut pas être estimée sur la base des données disponibles) ;
• troubles de l'audition, troubles de la vision, troubles de la parole, troubles de la coordination, troubles de la marche, pression exercée sur le cerveau (hypertension intracrânienne et pseudo-tumeur cérébrale) ;
• éruptions cutanées diverses ;
• aggravation des symptômes de la myasthénie (voir rubrique 2 : Avertissements et précautions) ;
• augmentation du nombre de cellules du foie (nécrose hépatique) aboutissant très rarement à une insuffisance hépatique mortelle ;
• hépatite, destruction des cellules du foie (nécrose hépatique) aboutissant très rarement à une insuffisance hépatique mortelle ;
• sensibilité à la lumière (voir rubrique 2 : Avertissements et précautions), petits saignements sous forme de points rouges sous la peau (pétéchies) ;
• sensation de chaleur ou de cristaux dans les urines, inflammation des voies urinaires ;
• insomnie excessive ;
• troubles de la coordination dans le sang d'une enzyme issue du pancréas (amylase).

5. COMMENT CONSERVER CIPRO 200 mg/100 mL, solution pour perfusion (IV) ?

- Tenir le médicament hors de la vue et de la portée des enfants.
• Ne pas ouvrir le flacon de CIPRO 200 mg/100 mL, solution pour perfusion (IV) avant utilisation. Une fois ouvert, le flacon doit être utilisé immédiatement. La date de péremption fait référence au dernier jour de ce mois.
A conserver à l'abri de la lumière.
Ne pas mettre le flacon au réfrigérateur ni au congélateur.
Un point de vue microbiologique, même si la méthode d'ouverture et de mélange d'autres médicaments previent tout risque de contamination, il est recommandé d'utiliser le médicament immédiatement, les conditions et le temps de stockage en cours d'utilisation relèvent de la responsabilité de l'utilisateur.
Ne geler aucun médicament au tout-d'égout ni avec des ordres médicaux. Demandez à votre pharmacien d'éliminer les médicaments périmés.
6. CONTENU DE L'EMBALLAGE ET AUTRES INFORMATIONS
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est un médicament à usage hospitalier.
La substance active est : la ciprofloxacine.
Chaque flacon en verre de 100 mL de solution pour perfusion contient 200 mg de ciprofloxacine.
Les autres composants sont :
• acide lactique, chlorure de sodium, sac pour préparations injectables.
CIPRO 200 mg/100 mL, solution pour perfusion (IV) est un médicament à usage hospitalier.
Le médicament est sous forme de flacon de 100mL, incluant de verre neutre type I muni d'un bouchon et d'une capsule dans une boîte de 01 flacon et de 12 flacons.

7. D'autres informations

- L'AMN : CIPRO 200 mg/100mL ; boîte de 01 flacon de 100 mL 923292H
CIPRO 200 mg/100mL ; boîte de 12 flacons de 100 mL 923292H
Détails de fabrication et/ou de mise sur le marché :
Les laboratoires Medis - Route de Tunis - KM 7 - BP 306 - 8000 Nabeul - Tunisie
Tél : +33 (0) 47 23 50 016 - Email : cipro@medis.com
La dernière date à laquelle cette notice a été révisée est : 03 / 2021

8. GARDER LES MÉDICAMENTS HORS DE LA PORTÉE DES ENFANTS

• Un médicament est un produit mais pas un jouet.
• Un médicament est un produit qui agit sur votre santé et sa consommation non-conforme aux prescriptions vous expose à un danger.
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CIPRO 200 mg/100 mL solution for infusion (IV) Ciprofloxacin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- Some medicines have to be prescribed for you only. Do not pass this on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).

What is this leaflet for?

1. What is CIPRO 200 mg/100 mL solution for infusion (IV) and in what case is it used?
2. What you need to know before you take CIPRO 200 mg/100 mL solution for infusion (IV)?
3. How to take CIPRO 200 mg/100 mL solution for infusion (IV)?
4. What are the possible side effects?
5. How to store CIPRO 200 mg/100 mL solution for infusion (IV)?

1. WHAT IS CIPRO 200 mg/100 mL solution per infusion (IV) AND IN WHAT CASE IS IT USED?
Ciprofloxacin belongs to the class of drugs called fluoroquinolones. It works by killing the infectious bacteria. It is only active on some specific strains of bacteria.

CIPRO 200 mg/100 mL solution for infusion (IV) is indicated in the treatment of the following infections. Special attention should be given to the treatment of severe infections with ciprofloxacin before starting treatment. Official recommendations concerning the appropriate use of antibacterials should be taken into account.

- Adults**
- Lower respiratory tract infections due to Gram-negative bacteria
 - exacerbations of chronic obstructive pulmonary disease
 - bronchopulmonary infections in cases of cystic fibrosis or bronchiectasis
 - purulent media chronic otitis
 - Acute exacerbations of chronic sinusitis, particularly due to Gram-negative bacteria
 - Urinary infections
 - Reproductive tract Infections
 - High susceptibility, including infections due to susceptible strains of *Neisseria gonorrhoeae*
 - High susceptibility, including infections caused by susceptible *Neisseria gonorrhoeae* strains
 - Gastrointestinal infections (eg traveler's diarrhea)
 - Skin and soft tissue infections caused by Gram-negative bacteria
 - External malignant otitis
 - Bone and joint infections
 - Anthrax disease (post-exposure prophylaxis and curative treatment)
- Ciprofloxacin can be used for the treatment of febrile neutropenic patients whose bacterial origin is suspected.

Children and adolescents

- Bronchopulmonary infections in cystic fibrosis caused by *Pseudomonas aeruginosa*
- Complicated urinary infections and pyelonephritis
- Anthrax disease (post-exposure prophylaxis and curative treatment)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CIPRO 200 mg/100 mL solution for infusion (IV)?
Never take CIPRO 200 mg/100 mL solution for infusion (IV):

- if you are allergic to the active substance, other quinolones or any of the other ingredients of this medicine (listed in section 6)
- if you are taking tizanidine (see section 2). Other medicines and CIPRO 200 mg/100 mL solution for infusion (IV).

Warnings and precautions

Talk to your doctor before you receive CIPRO 200 mg/100 mL solution for infusion (IV):

- if you have already had kidney problems as it may be necessary to adjust your treatment;
- if you suffer from vertigo or other otoneurological conditions;
- if you have already had tendon problems with antibiotics from the same family as CIPRO;
- if you have diabetes because you may be at risk of hypoglycaemia with ciprofloxacin;
- if you suffer from myasthenia (a rare disease that causes muscle weakness) because symptoms may be exacerbated;
- if your electrocardiogram (ECG) should be used with caution if you are born with or have a family history of QT prolongation (seen on an ECG tracing, recording of the electrical tracing of the heart), if you have an electrolyte imbalance in the blood (including low levels of potassium or magnesium in the blood), if you have a very slow heart rate (bradycardia), if you have a weakened heart (heart failure), if you already have had a heart attack (myocardial infarction), if you are a woman or a senior, or if you are taking other medications that may cause some ECG abnormalities (see section 2). Other medicines and CIPRO 200 mg/100 mL solution for infusion (IV);
- if you are taking tizanidine (see section 2). Other medicines and CIPRO 200 mg/100 mL solution for infusion (IV);

because you could then risk presenting anemia with ciprofloxacin.

3. HOW TO TAKE CIPRO 200 mg/100 mL solution for infusion (IV)?

For the treatment of some infections of the genital tract, your doctor may prescribe another antibiotic in combination with CIPRO. If no improvement in symptoms is observed after 3 days of treatment, consult your doctor.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS OF CIPRO 200 mg/100 mL solution for infusion (IV)?

Tell your doctor immediately if any of the following disorders occur during treatment with CIPRO. Your doctor will determine if the treatment with CIPRO should be stopped.

• **Severe allergic reactions** (such as anaphylaxis, shock, Angioedema). From the first dose, there is a low risk of developing a severe allergic reaction, manifested by the following symptoms: tightness in the chest, dizziness, feeling of malaise or weakness, or dizziness when standing up. If these symptoms occur, contact your doctor immediately as the reaction may be fatal.

• **Pain and swelling in the joints and tendinitis** may occur occasionally, especially if you are elderly and also if you are treated with corticoids. Inflammation and rupture of the tendons can occur from the first 48 hours of treatment and up to several months after stopping treatment with CIPRO. At the slightest sign of pain or inflammation of the joints or tendons, tell your doctor immediately to advise you to stop your treatment and put the painful area to rest. Avoid unnecessary efforts as this may increase the risk of tendon rupture.

• If you suffer from **epilepsy** or other **neurological disease** such as cerebral ischemia or stroke, neurological side effects (such as dizziness, vertigo, headache) with CIPRO should be stopped; contact your doctor immediately.

• You may have symptoms suggestive of **neuropathy**, such as pain, burning, tingling, numbness, and / or muscle weakness. If such symptoms occur, treatment with CIPRO should be discontinued; contact your doctor immediately.

• If you suffer from **depression** or other **psychiatric disorders** (such as depression or psychosis), your symptoms may worsen during treatment with CIPRO. In rare cases, depression or psychosis can progress to suicidal thoughts, suicide attempts, or suicide. If such reactions occur, contact your doctor immediately.

• Cases of **hypoglycaemia** have been reported, most often in diabetic patients, mainly in the elderly population. If this side effect occurs, contact your doctor immediately.

• **Diarrhea** can occur while taking antibiotics, including CIPRO, and even several weeks after the end of treatment. If diarrhea becomes severe or persistent or you notice blood or mucus in your stool, treatment with CIPRO should be stopped; contact your doctor immediately as this may be a sign of risk. Do not take medicines to stop or slow down the intestinal transit.

• If your eyesight worsens or you notice any effect on the eyes, consult an ophthalmologist immediately.

• Your skin becomes more sensitive to the sun and ultraviolet (UV) rays when you receive CIPRO. Avoid prolonged exposure to the sun or artificial UV rays such as tanning booths.

• Tell your doctor if you are taking CIPRO if you require **blood or urine sample**.

• If you have **kidney problems**, tell your doctor because the dose of CIPRO should eventually be adapted.

• CIPRO can cause **liver problems**. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), or stools that are pale or grey, contact your doctor immediately.

• If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharyngitis or urinary problems you should see your doctor immediately.

• Tell your doctor if you are taking CIPRO if you are taking CIPRO at the same time as these medications; could impact on the therapeutic effects of these products, and increase the probability of occurrence of side effects.

Tell your doctor if you are taking:

- cloxacillin, cloxacillin sodium, acenocoumarol, phenprocoumon or flunarizine or other oral anticoagulants (to thin the blood)
- probenecid (to treat gout)
- methotrexate (to treat some types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (to treat respiratory problems)
- zidovudine (to treat HIV infection)
- diltiazem (to treat high blood pressure)
- olanzapine (an antipsychotic)
- cizapride (to treat some psychiatric diseases)
- tizanidine (to treat muscle spasticity disorders related to multiple sclerosis)
- phenytoin (to treat epilepsy)
- ciclosporin (to treat skin diseases, rheumatoid arthritis, and organ transplants)
- other medicines that may affect your heart rate; medicines belonging to the group of antiarrhythmic medication (eg quinidine, procainamide, disopyramide, amiodarone, sotalol, dofetilide, Bepridil, flecainide, anti-depressants, certain antibiotics (which belong to the macrolides family), some antipsychotics
- zolpidem (to treat sleep disorders).

CIPRO may increase the concentration of the following medicines in your blood:

- ciprofloxacin
- caffeine
- diltiazem (to treat depression, nerve damage related to diabetes or urinary incontinence)
- lidocaine (to treat heart disease or anesthetic use)
- sildenafil (for example, in erectile dysfunction)
- acetaminolone (to treat depression)

CIPRO 200 mg/100 mL solution for infusion (IV) with food and drink

Food and drink have no effect on your CIPRO treatment.

Pregnancy and breastfeeding

If you're pregnant or if you think you are pregnant or planning pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

It is recommended to avoid using CIPRO during pregnancy.

Do not use CIPRO while breastfeeding passes into breast milk and could affect your child's health.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

CIPRO can lower your alertness. Neurological side effects may occur. Therefore, make sure you know how you can take CIPRO while driving or using machines. If in doubt, talk to your doctor.

CIPRO 200 mg/100 mL solution for infusion (IV) contains sodium

This content should be taken into account in patients for whom control of sodium intake is required.

HOW TO STORE CIPRO 200 mg/100 mL solution for infusion (IV)?

Your doctor will explain exactly how much CIPRO will be given, how often and for how long. This will depend on the type of infection and its severity.

Call your doctor if you have kidney problems because the dose of medicine to be adapted.
Dosage
The treatment usually lasts from 5 to 21 days but can be longer in case of severe infection.

The health professional will inject each dose into your blood stream as a slow infusion into one of your veins. In children, the infusion will last 60 minutes.

In adults, it takes 30 minutes for the administration of the 200 mg solution of CIPRO. Administering the infusion slowly helps prevent the occurrence of immediate side effects.

Remember to drink plenty of fluids while taking this medicine.
If you have taken more CIPRO 200 mg/100 mL solution for infusion (IV) than you should :
Not applicable.

If you forget to take CIPRO 200 mg/100 mL solution for infusion (IV) :
Not applicable.

If you stop taking CIPRO 200 mg/100 mL solution for infusion (IV) :
It is important that you follow the treatment until the end even if you start to feel better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and the symptoms of the infection may reappear or worsen. You may also develop bacterial resistance to this antibiotic.

4. POSSIBLE SIDE EFFECTS OF CIPRO 200 mg/100 mL solution for infusion (IV) :
Like all medicines, this medicine can cause side effects, although not everybody gets them.
The most serious side effects that you can recognize yourself are listed in the section below.

CIPRO should be stopped and you should contact your doctor immediately to consider another antibiotic treatment, if you notice any of the following symptoms which are listed below:

Uncommon side effects (may affect up to 1 in 100 people)

- seizures (see section 2 : Warnings and precautions)

Rare side effects (may affect up to 1 in 1 000 people)

- severe and sudden allergic reaction manifested by symptoms such as tightness in the chest, dizziness, feeling of malaise or weakness, or dizziness when standing (anaphylactic shock) (see section 2 : Warnings and precautions)
- rupture of the tendons, particularly of the large tendon located at the back of the ankle (Achilles tendon) (see section 2 : Warnings and precautions)

Very rare side effects (may affect up to 1 in 10 000 people)

- severe and sudden allergic reaction manifested by symptoms such as tightness in the chest, dizziness, feeling of malaise or weakness, or the occurrence of dizziness when standing (anaphylactic reaction) (see section 2 : Warnings and precautions)
- muscle weakness, inflammation of the tendons which can lead to tendon rupture, particularly of the large tendon located at the ankle (Achilles tendon) (see section 2 : Warnings and precautions)
- severe skin rash that can be life-threatening, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes, and other mucous membranes (Stevens-Johnson syndrome, Erythema multiforme) may develop into blisters or a detachment of the skin all over the body (Stevens-Johnson syndrome, Erythema multiforme)

Not known frequency (frequency can not be estimated based on the available data)

- unusual sensations of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy) (see section 2 : Warnings and precautions)
- side effect that causes rash, fever, inflammation of internal organs, hematological abnormalities and systemic disease (drug hypersensitivity syndrome with eosinophilia and systemic symptoms syndrome called DRESS [Drug Reaction with Eosinophilia and Systemic Symptom], PEAG / Generalized Acute Exanthematous Pustulosis)

Other side effects which have been observed during treatment with Cipro are listed below by frequency of occurrence:

- **Common side effects (may affect up to 1 in 10 people)**
 - nausea, diarrhea, vomiting
 - joint pain and inflammation of the joints in children
 - local reaction at the injection site, rash
 - temporary elevation of certain liver enzymes present in the blood (transaminases).
- **Uncommon side effects (may affect up to 1 in 100 people)**
 - joint pain in adults
 - fungal infections (due to fungi)
 - high rate of one type of white blood cell (eosinophils), increase or decrease in the amount of blood clotting factors (platelets)
 - decreased appetite
 - hyperactivity, agitation, confusion, disorientation, hallucinations
 - headaches, dizziness, sleep disorders, taste disorders, tingling sensation, unusual sensitivity to sensory stimuli, vertigo
 - impaired vision, including double vision
 - loss of hearing
 - heartbeat acceleration (tachycardia)
 - dilation of blood vessels (vasodilatation), lowering of blood pressure
 - abdominal pain, digestive problems such as stomach problems (indigestion / heartburn) or flatulence
 - hepatic disorders, increased amount of a substance in the blood (bilirubin), jaundice (cholestatic jaundice)
 - itching, hives
 - impaired renal function, renal failure
 - muscle and bone pain, general fatigue (asthenia), fever, fluid retention
- **Rare side effects (may affect up to 1 in 1 000 people)**
 - unusual levels of a substance present in the blood (alkaline phosphatase).

Rare side effects (may affect up to 1 in 1 000 people)

- muscle pain, inflammation of the joints, increased muscle tone and cramps
- inflammation of the intestines (colitis) related to the use of antibiotics (which can be fatal in very rare cases)

Very rare side effects (may affect up to 1 in 10 000 people)

- change in the number of certain white blood cells or red blood cells (leukopenia, leukocytosis, neutropenia, anemia) decrease in the number of red blood cells, white blood cells and platelets (pancytopenia) which can be fatal
- allergic reaction, allergic swelling (edema) or rapid swelling of the skin and mucous membranes (angioedema) (see section 2 : Warnings and precautions)
- increased blood sugar level (hyperglycaemia) (see section 2 : Warnings and precautions)
- anxiety reactions, strange dreams, depression (which may lead to suicidal thoughts, suicide attempts or suicide), suicidal thoughts or actions (psychotic reactions that may lead to suicidal thoughts, suicide attempts or suicide) (see section 2 : Warnings and precautions)
- decreased sensitivity of the skin, tremors, migraine, disorders of smell (olfactory disorders)
- ringing, hearing disorders
- fainting, inflammation of the lining of blood vessels (vasculitis)
- shortness of breath, including asthmatic symptoms
- inflammation of the pancreas (pancreatitis)
- hepatitis, death of liver cells (liver necrosis) very rarely leading to liver failure putting your liver at risk (see section 2 : Warnings and precautions)
- sensitivity to light (see section 2 : Warnings and precautions), small bleeding in the form of red spots under the skin
- presence of blood or crystals in the urine, inflammation of the urinary tract
- excessive sweating
- increase in the concentration in the blood of an enzyme derived from the pancreas (amylase).

Very rare side effects (may affect up to 1 in 10 000 people)

- particular type of decline in the number of red blood cells in the blood (hemolytic anemia), very low number of certain white blood cells in the blood (see section 2 : Warnings and precautions)
- allergic reaction called serum sickness reaction (see section 2 : Warnings and precautions)
- coordination disorders, unsteady gait (gait disorders), pressure on the brain (intracranial hypertension and cerebral pseudotumor)
- disorders in color perception
- various skin rashes
- development of myasthenia symptoms (see section 2 : Warnings and precautions)

Unknown frequency (frequency can not be estimated based on available data)

- feeling of being excited (mania) or feeling of great optimism with hyperactivity (hypomania)
- abnormally fast, heartbeat, irregular heartbeat threatening your life, modified heart rhythm (called "QT interval prolongation") observed on ECG, recording of the electrical tracing of the heart)
- change in blood clotting (in patients treated with vitamin K antagonists).

Resting of side effects

If you get any side effects, talk to your doctor or pharmacist. This also applies to any undesirable effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you help your doctor and the manufacturer to improve the safety of the medicine.

5. HOW TO STORE CIPRO 200 mg/100 mL solution for infusion (IV)?
Keep this medicine out of sight and reach of children.
Do not use this medicine after the expiry date which is stated on the box and on the vial after "EXP". The expiry date refers to the last day of the stated month.

Store away from light.
Do not put the vial in the fridge or freezer.

From a microbiological point of view, even if the method of opening and mixing with other medicines prevents any risk of contamination, the product must be used immediately. If it is not used immediately, the responsibility of the user of the product affects your health. It is not used properly; it can be contaminated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to eliminate medicines you no longer use. These measures will help protect the environment.

NOTICE OF THE PACKAGING AND OTHER INFORMATION
What CIPRO 200 mg/100 mL solution for infusion (IV) contains

• The active substance is: ciprofloxacin.
Each glass bottle of CIPRO 200 mg/100 mL solution for infusion contains 200 mg of ciprofloxacin.

The other components are:
lactic acid, sodium chloride, water for injections.

What CIPRO 200 mg/100 mL solution for infusion (IV) looks like and content of the outer packaging
This medicine is under the form of a 100 mL bottle of neutral type I glass with a stopper and a capsule in a box of 1 bottle and 12 bottles.

Prescription and supply condition : List I
Medicine for hospital use.
MA N°:

CIPRO 200 mg/100 mL - Box of 01. bottle of 100 mL 92329010
CIPRO 200 mg/100 mL - Box of 12 bottles of 100 mL 92329251

Marketing Authorization Holder & Manufacturer :
Les Laboratoires Médix - Route de Tadmir - KM 7 - BP 206 - 8000 Nabeul - Tunisie
Tel : +216 72 235 006 / Fax : +216 72 235 016 / E-mail : contact@labmedix.com

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This is a Medicine

- A medicine is a product but not like any other product
- It is not a product that affects your health. It is not used properly; it can be contaminated.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, health threatening.
- Follow your pharmacist advice.
- Don't give your child medicines without your doctor's advice.
- Don't stop the use of the treatment on your own during the prescribed time
- Don't re-use, don't increase the dose without doctor's advice.

Keep the medicines out of reach of children