SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

CeftriNor 1,000 mg powder and solvent for solution for intramuscular injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CeftriNor 1,000 mg
Each vial contains 1,000 mg of ceftriaxone (as ceftriaxone sodium).
Each solvent ampoule contains 35 mg of lidocaine hydrochloride.
Once reconstituted with those 3.5 ml of solvent with lidocaine from the ampoule, the concentration of the solution is 285.71 mg of ceftriaxone (as sodium ceftriaxone) per ml.
Excipient with known effect:
Each vial contains 83.24 mg of sodium.
Each ml of reconstituted solution contains 23.78 mg of sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.
Each vial contains an almost white or yellowish powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ceftriaxone is indicated for the treatment of serious infections caused by microorganisms sensitive to ceftriaxone (see sections 4.2 and 5.1):

- Bacterial meningitis
- Abdominal infections, such as peritonitis and infections of the biliary tract
- Osteoarticular infections
- Complicated skin and soft tissue infections
- Complicated urinary tract infections (including pyelonephritis)
- Respiratory tract infections
- Genital tract infections (including gonococcal infection)
- Phases II and III of Lyme disease
- Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Prophylaxis of post-surgical infections, in contaminated or potentially contaminated surgery, mainly cardiovascular surgery, urological procedures and colorectal surgery.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

The selected dose to treat an individual infection must take into account the microorganisms and sensitivity to the antibacterial agent, place and severity of infection and age and weight of the patient, as well as:

The duration of treatment varies depending on the severity of the infection and the patient's response and will have to be, in general, as shortest as possible. In general, administration of ceftriaxone should be continued for at least 48 to 72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.

- *Adults and children over 12 years of age and children ≥50 kg*:

The usual dose is 1-2 g of ceftriaxone, administered once a day (every 24 hours). In cases of serious infections or in infections caused by moderately sensitive microorganisms the dose can be raised up to a maximum of 4 g administered once a day.

Non-complicated gonococcal disease.
For the treatment of gonococcal disease (strains penicillinase-producers or not), a single 250 mg intramuscular dose is recommended.

Phases II and III of Lyme disease
It is recommended to administer a dose of 50 mg/kg of weight up to a maximum of 2 g daily once a day for 14 days.

Perioperative prophylaxis
A single dose of 1-2 g, 30-90 minutes before surgery. In colorectal surgery, another antibiotic of adequate spectrum against anaerobes should be associated.

Combination therapy:
In infections caused by Gram-negative germs, the association with aminoglycosides may be necessary, especially in case of serious or potentially life-threating infections.

Patients with renal impairment
In case of patients with impaired renal function, it is not necessary to reduce the dose as long as the liver function remains normal. Only in cases of creatinine clearance <10 ml/min, should the ceftriaxone dosage not exceed 2 g daily.
Patients undergoing haemodialysis or peritoneal dialysis do not need an additional dose after the dialysis; in any case, the clinical situation of the patient will be monitored in case dose adjustments are required.

Patients with hepatic impairment
In case of impaired liver function, it is not necessary to reduce the dose if the renal function is normal.

In the event of severe renal and hepatic dysfunction, the dosage of ceftriaxone should not exceed 2 g daily unless plasma concentrations are regularly determined, and dosage is adjusted if necessary.

Elderly patients
It is not necessary to modify the recommended doses for adults provided that there is no renal and/or hepatic function impairment

Paediatric population
Neonates (up to 14 days): 20 to 50 mg/kg of weight, administered in a single dose with no differences between full-term and preterm infants. The dose of 50 mg/kg of weight must not be exceeded.
Neonates (15-28 days), infants (28 days to 23 months) and children (2 to 12 years): a single daily dose of 20-80 mg/kg of weight.

Bacterial meningitis in new-born babies (15-28 days), breast-fed babies (from 28 days to 23 months) and children (from 2 to 12 years):
Treatment will start with doses of 100 mg/kg (without exceeding 4 g) once a day. As soon as the causal germ is identified and its sensitivity is determined, the dose can be adjusted accordingly.

Depending on the dosage, there are other presentations more suitable for the different dosing regimens.

Method of administration.
Intramuscular route

This medicinal product is to be reconstituted before use. The reconstituted solution is limpid and yellow or slightly yellow. For reconstitution conditions, see section 6.6.

Only for intramuscular route: Intramuscular injections should be injected well within the bulk of a relatively large muscle. It is recommended not to inject more than 1 at one site.

Solutions containing calcium (e.g. Ringer solution, Hartmann solution) should not be used to reconstitute ceftriaxone vials or to dilute reconstituted vials when they are to be administered through the IV route, as precipitates may be formed. Ceftriaxone-calcium precipitates may also be formed when ceftriaxone is mixed with solutions containing calcium in the same line as the IV administration. Therefore, ceftriaxone and solutions containing calcium should not be mixed nor concomitantly administered (see sections 4.3, 4.4 and 6.2)

4.3 Contraindications

It is contraindicated in:

- Preterm infants up to the corrected age of 41 weeks (weeks of pregnancy + weeks of life)
- Full-term infants (up to 28 days of age) with:
    - jaundice, or those with hypoalbuminemia or acidosis, since with these conditions, the bilirubin binding is likely to be altered
    - If treatment with IV calcium or infusions with calcium are needed (or it is thought that they will be needed), because of the precipitation risk of ceftriaxone with calcium (see section 4.4, 4.8 and 6.2).

CeftriNor is contraindicated in patients with hypersensitivity to the active ingredient or to any of the excipients included in section 6.1 or to other cephalosporins. Likewise, it is contraindicated in patients with immediate or serious hypersensitivity to penicillins or to any other beta-lactam antibiotics.

4.4 Special warnings and precautions for use

Before initiating therapy with ceftriaxone, enquiry should be made concerning possible previous hypersensitivity reactions to penicillins and cephalosporins. The possibility of allergic cross-reactions should be taken into account in patients hypersensitive to penicillins.

Serious, and occasionally fatal, hypersensitivity reactions (anaphylaxis) have been observed in patients treated with beta-lactam antibiotics. If allergic reaction occurs, ceftriaxone treatment shall be discontinued, and a supporting treatment will be instituted.

Severe cutaneous adverse reactions (Stevens Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis **and drug reaction with eosinophilia and systemic symptoms) which can be life-threatening or fatal have been reported in association of ceftriaxone treatment**; however, the frequency of these events is not known (see section 4.8).

Jarisch-Herxheimer reaction (JHR)

Some patients with spirochete infections may experience a Jarisch-Herxheimer reaction (JHR) shortly after ceftriaxone treatment is started. The Jarisch-Herxheimer reaction is usually a self–limiting condition or can be managed by symptomatic treatment. The antibiotic treatment should not be discontinued if such reaction occurs.

The use of antibiotics, including ceftriaxone, may produce changes in the normal flora of the colon with an overgrowth of *Clostridium difficile*, whose toxin can trigger symptoms of pseudomembranous colitis which causes fever, abdominal pain and diarrhoea that may be bloody. It may appear during treatment of weeks after it has been completed. Mild cases usually respond to treatment discontinuation, but moderate to severe cases may require adequate replacement of hydro-electrolytes and an effective antibiotic against *C. difficile*.

Anticholinergic and anti-peristaltic drugs may exacerbate the state of the patient.

As it happens with antibacterial agents, prolonged use of ceftriaxone may lead to superinfections caused by resistant microorganisms.

The administration of doses of ceftriaxone generally higher than the recommended, a treatment longer than 14 days, the presence of dehydration or renal failure may give rise to precipitates of calcium ceftriaxone in the gallbladder which in the ultrasound scan may be read as biliary lithiasis and that usually disappear once the treatment is concluded or after treatment is withdrawn. These signs have been rarely associated with symptoms. Your doctor should consider the convenience of suspending treatment in symptomatic cases. If symptoms appear, a conservative non-surgical treatment is recommended.

These biliary precipitates affect children more frequently, since they receive comparatively higher doses if they are adapted based on their body weight. Therefore, doses higher than 80 mg/kg of weight should not be administered since there is an increase of the risk of biliary precipitation.

Cases of pancreatitis have been rarely described in patients treated with ceftriaxone, whose possible aetiology is biliary obstruction. Most of the patients concomitantly presented risk factors of biliary stasis and biliary sludge, such as a previous surgical procedure, a serious illness or parenteral nutrition. However, a trigger or cofactor role of ceftriaxone-related biliary precipitation cannot be discarded.

Among the cases of ceftriaxone precipitation at renal level, most of them are given in children older than three years old treated with high daily doses (e.g., ≥80 mg/kg/day), or with total doses above 10 g, and presenting other risk factors (e.g. fluid restriction, bed confinement, etc.). This effect may be symptomatic or asymptomatic, may lead to renal failure and is reversible when discontinuing treatment.

In prolonged treatments with ceftriaxone, the haematological profile should be regularly monitored.

Encephalopathy

Encephalopathy has been reported with the use of ceftriaxone (see section 4.8), particularly in elderly patients with severe renal impairment (see section 4.2) or central nervous system disorders. If ceftriaxone-associated encephalopathy is suspected (e.g. decreased level of consciousness, altered mental state, myoclonus, convulsions), discontinuation of ceftriaxone should be considered.

Interference with diagnostic tests

The test of Coombs can rarely result in false positives in patients treated with ceftriaxone. Ceftriaxone, like other antibiotics, may yield false positives in tests for galactosemia.

Likewise, non-enzymatic methods to determine glucose in urine may yield false-positive results. This is why during treatment with ceftriaxone, determination of glucose in urine must be carried out by enzymatic methods.

CeftriNor for intramuscular administration contains lidocaine in the solvent ampoule to increase local tolerance towards administration.

It should neither be used intravenously nor in patients with a history of hypersensitivity to lidocaine.

Important information about excipients

CeftriNor 1,000 mg:

This medicine contains 83.24 mg of sodium per vial, equivalent to 4.162% of the maximum daily intake of 2 g of sodium recommended by the WHO for adults.

It contains 23.78 mg (1.03 mmol) of sodium per ml of reconstituted solution.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant use of ceftriaxone with bacteriostatic antibiotics is not recommended, especially in the case of acute infections.

An antagonist effect has been observed *in vitro* with the combination of ceftriaxone and chloramphenicol.

Simultaneous administration of probenecid at high doses (1 or 2 grams daily) may inhibit biliary excretion of ceftriaxone. Contrary to other cephalosporins, probenecid does not inhibit tubular secretion of ceftriaxone.

The simultaneous administration of ceftriaxone may adversely affect the efficacy of hormonal contraceptives. Therefore, it is recommended to take additional measures during treatment and within the following month.

4.6 Fertility, pregnancy, and lactation

Pregnancy
No clinical data on the use of ceftriaxone in pregnant women are available. No experimental tests on embryopathic or teratogenic effects in animals are available. Ceftriaxone should only be used during pregnancy if benefits outweigh the possible risks for the foetus.

Breast-feeding
Given that ceftriaxone is excreted in breast milk, it will be used with caution in breast-feeding women.

4.7 Effects on ability to drive and use machines

The influence on the ability to drive and use machines is negligible, although it must be taken into account that dizziness may occasionally occur.

4.8 Undesirable effects

Rarely severe adverse reactions have been reported (≥1/10,000 to <1/1,000) in preterm and full-term infants (age <28 days) who had been treated with intravenous ceftriaxone and calcium. These reactions have caused death in some cases. Precipitates of post-mortem ceftriaxone-calcium have been observed in lungs and kidneys.

High risk of precipitates in neonates is due to the low blood volume and the longer half-life of ceftriaxone in comparison with adults (see sections 4.3, 4.4. and 5.2).

The following convention has been used for the classification of frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available data).

System organ class	Undesirable effects	Frequency categories
Infections and infestations	Vulvovaginitis	Rare
Blood and lymphatic system disorders	Anaemia (including haemolytic anaemia)	Rare
	Leukopenia	Rare
	Granulocytopenia Thrombocytopenia	Rare
	Eosinophilia	Rare
	Coagulation disorders	Very rare
	Agranulocytosis (especially after 10 days of treatment or after high doses).	Very rare
Immune system disorders	Anaphylactic or anaphylactoid reactions	Rare
	Urticaria	Rare
	Jarisch-Herxheimer reaction (see section 4.4)	Not known
Nervous system disorders	Headache	Rare
	Dizziness	Rare
	Encephalopathy	Rare
Gastrointestinal disorders	Diarrhoea	Common
	Nausea	Common
	Stomatitis	Common
	Glossitis	Common
	Pseudomembranous colitis (see section 4.4)	Very rare
	Pancreatitis	Very rare
	Gastrointestinal bleeding	Very rare
Hepatobiliary disorders	Symptomatic precipitation of calcium ceftriaxone in the gallbladder (see section 4.4)	Rare
	Increased liver enzymes	Rare
	Hepatitis[c]	Not known
	Hepatitis cholestatic[b,c]	Not known
Skin and subcutaneous tissue disorders	Rash	Uncommon
	Allergic dermatitis	Uncommon
	Rash	Uncommon
	Oedema	Uncommon
	Erythema multiforme	Uncommon
	Stevens-Johnson syndrome	Very rare
	Toxic epidermal necrolysis or Lyell syndrome	Very rare
	Drug reaction with eosinophilia and systemic symptoms (see section 4.4)	Not known
Renal and urinary disorders	Oliguria	Rare
	Increased serum creatinine	Rare
	Precipitation of calcium ceftriaxone in the kidneys in paediatric patients (see section	Very rare

	4.4)	
	Haematuria	Very rare
General disorders and administration site conditions	Fever	Rare
	Chills	Rare

b See section 4.4.
c Usually reversible upon discontinuation of ceftriaxone

Transient pain may occur at intramuscular injection site, and it is more likely with high doses.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.*

4.9 Overdose
Overdose with cephalosporins for parenteral administration may cause convulsions as well as gastrointestinal disorders. In case of overdose, drug administration should be discontinued, and a supportive symptomatic treatment should be implemented. There is no specific antidote and ceftriaxone is not eliminated by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cephalosporins of third generation, ATC code: J01DD.

Ceftriaxone is a wide-spectrum long-acting cephalosporin for parenteral use. Its bactericidal activity results from the inhibition of the cell wall synthesis.

Resistance

Ceftriaxone may be active against organisms producing some types of beta-lactamases, for example TEM-1. However, there are beta-lactamases that can hydrolyse cephalosporins and that can inactivate ceftriaxone, such as the extended-spectrum beta-lactamases present in some species such as *Klebsiella* spp. and *Escherichia coli.* This is why, despite its apparent *in vitro* sensitivity, they must be considered resistant from a clinical point of view. Likewise, some strains of *Enterobacter* spp., *Citrobacter freundii*, *Morganella* spp., *Serratia* spp. and *Providencia* spp. produce inducible chromosomal cephalosporinases, such as AmpC. The stable induction or derepression of these chromosomal beta-lactamases before or during their exposure to cephalosporins produces resistance to all cephalosporins.

Ceftriaxone is not active against the majority of bacteria presenting penicillin-binding proteins with a reduced affinity for beta-lactam medicines, such as the case of penicillin-resistant *Streptococcus pneumoniae*. Resistance may also be due to the bacterial impermeability or to the presence of efflux pumps. The same microorganism may host more than one of these four means of resistance.

Breakpoints
The test with cefepime is performed using standard dilution series. The following minimum inhibitory concentrations for sensitive and resistant germs have been determined:

EUCAST (European Committee on Antimicrobial Susceptibility Testing version 6.0 2016-01-01) breakpoints

Microorganism	**Susceptibility**	**Resistance**
- *Enterobacteriaceae*	≤1	>2
- *Streptococcus pneumoniae*	≤0.5	>2

- Viridans group streptococci	≤0.5	>0.5
- Haemophilus influenzae	≤0.125	>0,125
Moraxella catarrhalis	≤1	>2
- Neisseria gonorrhoeae	≤0.125	>0,125
- Neisseria meningitidis	≤0.125	>0,125

The prevalence of resistance may vary geographically and with time for selected species, and local information on resistance is advisable, particularly when it comes to severe infections. An expert should be sought for advice as needed when the prevalence of resistance is such that the usefulness of the agent in at least some types of infections is questionable. The following information just provides an approximate idea of the probability that the microorganism is sensitive to ceftriaxone.

Commonly sensitive microorganisms

Gram-positive aerobes

Staphylococcus spp. coagulase-negative

*Staphylococcus aureus**

Streptococcus spp.

*Streptococcus pyogenes**

Streptococci from group B (including S. agalactiae)

*Streptococcus pneumoniae**

Streptococcus viridans **Gram- negative aerobes**

Citrobacter spp.

Citrobacter diversus

Citrobacter freundii

*Escherichia coli**

*Haemophilus influenzae**

*Haemophilus parainfluenzae**

Klebsiella spp.

*Klebsiella pneumoniae**

*Klebsiella oxytoca**

*Moraxella catarrhalis**

Morganella morganii

*Neisseria gonorrhoeae**

*Neisseria meningitidis**

*Proteus mirabilis**

*Proteus vulgaris**

Providencia spp.

Salmonella spp.

Serratia spp.

Serratia marcescens

Shigella spp.

Borrelia burgdoferi
<u>Microorganisms for which acquired resistance may be a problem</u> **Gram-positive aerobes** *Staphylococcus epidermidis** **Gram-negative aerobes** *Enterobacter* spp. *Enterobacter aerogenes** *Enterobacter cloacae**
<u>Resistant microorganisms</u> **Gram-positive aerobes** *Enterococcus* spp. *Enterococcus faecalis* *Enterococcus faecium* *Listeria monocytogenes* *Staphylococcus* spp. methicillin-resistant *Staphylococcus aureus* methicillin-resistant **Gram-negative aerobes** *Aeromonas* spp. *Achromobacter* spp. *Acinetobacter* spp. *Alcaligenes* spp. *Flavobacterium* spp. *Pseudomonas* spp. *Pseudomonas aeruginosa* **Anaerobes** *Bacteroides fragilis* *Bacteroides spp* **Other** *Chlamydia* *Mycobacteria* *Mycoplama* *Rickettsia* spp.

*Clinical efficacy has been shown for sensitive isolated in approved clinical indications.

5.2 Pharmacokinetic properties

Ceftriaxone presents non-linear dose-dependent pharmacokinetics for all basic pharmacokinetic parameters, with the exception of the elimination half-life.

Absorption:

The maximum plasma concentration after a single intramuscular dose of 1 g is around 81 mg/l and it is reached within 2-3 hours after its administration. The area under the curve "plasma concentration time", after intramuscular administration, is equivalent to the intravenous administration of an equivalent dose, indicating that the bioavailability of ceftriaxone administered intramuscularly is 100%.

Distribution and biotransformation:

Distribution volume of ceftriaxone is 7-12 L, being distributed to numerous body tissues and fluids. After an intravenous dose of 1-2 g, concentrations above the minimum inhibitory concentration may be found for most of the pathogens responsible for infections in more than 60 body tissues and fluids, including lung, heart, biliary and hepatic tracts, tonsils, middle ear and nasal mucosa, bones, and cerebrospinal, pleural, prostatic, and synovial fluids.

Ceftriaxone penetrates the inflamed meninges of neonates, infants, and children. In CSF, the ceftriaxone concentrations are >1.4 mg/l, 24 hours after intravenous administration of ceftriaxone at a dose of 50-100 mg/kg (neonates and infants, respectively). In CSF, the peak concentration of ceftriaxone is achieved about 4 hours after the intravenous injection, obtaining a medium value of 18 mg/l. In bacterial meningitis, the mean CSF diffusion is 17% with respect to the plasma concentration, whereas it is 4% in patients with aseptic meningitis.

In adult patients with meningitis, the injection of 50 mg/kg allows to achieve CSF concentrations within 2-24 hours that are several times higher than those minimum inhibitory concentrations necessary for most of the germs causing meningitis.

Ceftriaxone crosses the placenta and is excreted in human milk at low concentrations.

Protein binding:

Ceftriaxone is reversibly bound to plasma albumin. Such binding decreases as the concentration increases. Thus a 95% binding at plasma concentrations <100 mg/l reaches 85% at the concentration of 300 mg/l. Because of the lower content of albumin in the interstitial fluid, the proportion of ceftriaxone free in this fluid is higher than in plasma.

Metabolism:

Ceftriaxone is not systematically metabolised, only the intestinal flora transforms it into inactive metabolites.

Elimination:

Total plasma clearance is 10-22 ml/min. 50-60% of ceftriaxone is excreted as an unchanged substance in the urine whilst 40-50% is excreted via the bile, also as an unchanged substance.

The elimination half-life in adults is approximately 8 hours.

Special populations*:*

In the first week of life, 80% of the dose is excreted in the urine; around the first month, this decreases to levels similar to those of adults. In neonates of less than 8 days of age and in elderly patients above 75 years, the average elimination half-life is normally two or three-fold higher than in young adults.

In patients with renal or hepatic dysfunction, the pharmacokinetics of ceftriaxone are only minimally altered, and the elimination half-life increases very slightly; if only renal function is impaired, elimination

by bile is increased and, if only hepatic function is impaired, then renal elimination is increased (see section 4.2).

5.3 Preclinical safety data

Repeated dosing in animals revealed formation of biliary calculi in the gallbladder of dogs and at a lower degree, of monkeys.

Ceftriaxone has no effect on reproduction. It has not shown to possess any mutagenic activity.

6 . PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CeftriNor 1,000 mg
Powder vial: none
Solvent ampoule:
lidocaine hydrochloride
water for injection.

6.2 Incompatibilities

Solutions containing ceftriaxone should not be mixed, and other agents should not be added. Particularly, diluents containing calcium (e.g. Ringer solution, Hartmann solution) should not be used to reconstitute ceftriaxone vials or to dilute reconstituted vials when they are to be administered through the IV route, as precipitates may be formed. Ceftriaxone should not be mixed or concomitantly administered with solutions containing calcium (see sections 4.2, 4.3, 4.4 and 4.8 of the summary of product characteristics and section 6 of the package leaflet)

Ceftriaxone is incompatible with amsacrine, vancomycin, fluconazole, and aminoglycosides.

6.3 Shelf life

Unopened: 2 years.

After reconstitution: Reconstituted solutions keep their chemical and physical stability for 6 hours at 25 ºC and for 24 hours in a refrigerator (2ºC-8 ºC).

From a microbiological point of view, the product should be used immediately. If it is not immediately used, storage conditions and time prior to use are responsibility of the healthcare professional. This product should not be stored for more than 24 hours at a temperature between 2 and 8 ºC unless reconstitution took place under controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store below 30ºC. Store in the original package in order to protect from light.

For storage conditions after reconstitution of the medicinal product, see section 6.3

6.5 Nature and contents of container

CeftriNor 1,000 mg
Glass vial closed with a rubber stopper and sealed with a flip-off cap and a glass solvent ampoule.

It is supplied in carton boxes containing 1 powder vial and 1 solvent ampoule.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material that might have been in touch with it should be disposed of in accordance with local requirements.

Instructions for correct administration
This medicinal product is to be reconstituted before use.
For single use only. Unused solution must be discarded

The reconstituted solution is limpid and yellow or slightly yellow. During the storage of prepared solutions, an increase in colour may be produced without affecting the power of the drug.

ADMINISTER ONLY BY INTRAMUSCULAR INJECTION
Reconstitute each intravenous vial of CeftriNor intramuscular with its corresponding solvent ampoule.

CeftriNor 1,000 mg
For the intramuscular administration, dissolve the contents of the vial in 3.5 ml of solvent of the ampoule that comes with it (a solution of 35 mg/3.5 ml lidocaine hydrochloride).

Examine the solution before injecting it just in case there are particles or turbidity. If foreign particles are observed, discard the solution. Subsequently, inject into a relatively large muscle. Do not put more than 1 g in the same place.

Administration dose and schedule used depend on the age and weight of the patient, as well as on the severity of the infection.

The solution should not be mixed with solutions containing other antibiotics or in solutions different from those indicated above.

7. MARKETING AUTHORISATION HOLDER

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8. DATE OF REVISION OF THE TEXT

January 2021