CEFAXONE®

250 mg & 500 mg & 1g
Ceftriaxone
Powder for injection

FORMS, PRESENTATIONS AND COMPOSITION:

Powder for injection.

- **CEFAXONE® 1g (I.V.)**: Box of a vial of powder and an ampoule of solvent. This presentation is intended for hospital use.

Vial of powder:
Ceftriaxone.....1g
(as ceftriaxone sodium)
Ampoule of solvent:
Water for injection 10ml

- **CEFAXONE® 1g (I.M.):** Box of a vial of powder and an ampoule of solvent.

Vial of powder:
Ceftriaxone.....1g
(as ceftriaxone sodium)
Ampoule of solvent:
Lidocaïne hydrochloride 40mg
Water for injection 4ml

- **CEFAXONE® 500 mg (I.V., I.M. and S.C.):** Box of a vial of powder and an ampoule of solvent.

Vial of powder:
Ceftriaxone.....500mg
(as ceftriaxone sodium)
Ampoule of solvent:
Water for injection 5ml

- **CEFAXONE® 250 mg (I.V., I.M. and S.C.):** Box of a vial of powder and an ampoule of solvent.

Vial of powder:
Ceftriaxone.....250mg
(as ceftriaxone sodium)
Ampoule of solvent:
Water for injection.....5ml

- **CEFAXONE® 1g (I.M. / I.V.)**: Box of 10 vials of powder. This presentation is intended for hospital use.

Vial of powder:
Ceftriaxone.....1g
(as ceftriaxone sodium)

PHARMACO-THERAPEUTICAL CLASS:

Antibacterial antibiotic from betalactam family, from cephalosporins 3rd generation group.

INDICATIONS:

Hospital use :

- Severe infections due to germs sensitive to the ceftriaxone, particularly septicemia, endocarditis and the meningitis except those due to listeria monocytogenes.
- Lyme disease spread out during :
  - the early phase with meningitis (secondary stage),
  - the tardy phase with neurologic, articular systemic manifestations (tertiary stage).
- Prophylaxis of post operatory infections for the prostate transurethral resections.

City use:

- The continuation of treatments began in the hospital.
- Low respiratory Infections, in the severe forms, particularly for subjects at risks, mainly for the bacterial pneumopathies, acute rise of chronic bronchitis.
- Severe urinary Infections and/ or at resistant germs mainly: acute pyelonephritis, low urinary infections associated to a septic syndrome, acute rise of chronic prostatitis.
- Emergency antibiotherapy before hospitalization in case of clinical suspicion of Purpura fulminans.

CONTRAINDICATIONS:

- Allergy to antibiotics from cephalosporins group.
- Allergy to betatactams.
- For the premature until 41 WA corrected age.
- For the full term-new born babies until the age of 28 days in case of hyperbilirubinemia or calcium input.

For CEFAXONE® 1g (I.M.) containing the lidocaïne:

- Allergy to the lidocaïne or to other local anaesthetics from amide type.
- The reconstituted antibiotic must never be used trough I.V. way.
- Cardiogenic shock.
- Unpaced auriculoventricular block.
- Porphyria.

WARNINGS:

- The emergence of an allergic reaction imposes the treatment's stop.
- The prescription of cephalosporins necessitates a prior questioning.
- Before taking this medicament, prevent your doctor if you have had with a previous antibiotic, urticaria or other cutaneous eruptions, itching, angioedema.
- In case of pain in right hypochondrium and/or abdominal pain, it is necessary to practice an echography to research a biliary sludge or renal lithiasis.

PRECAUTIONS OF USE:

- Do not inject by IM way more than 1g in the same side.
- In case of history of renal lithiasis or hypercalciuria.
- In case of prolonged treatment, some controls of the blood formula are necessary.
- In case of severe renal failure or associated renal and hepatic failures, adapt the posology in function of the creatinine clearance.
- The ceftriaxone shouldn't be mixed to solutions containing calcium.
- When some calcium solutions are administered, it is recommended to perfuse the ceftriaxone on a separated way and in a period in which calcium is not perfused, even if the alimentary ways are different.
- This medicament contains sodium. This medicament contains 20.75 mg of sodium for CEFAXONE® 250 mg, 41.50 mg of sodium for CEFAXONE® 500 mg and 83 mg of sodium for CEFAXONE® 1 g. Take into account for patients controlling their food input in sodium.

INTERACTIONS:

In order to avoid possible interactions between many medicaments, you have to signal systematically any other concomitant treatment to your doctor.

PREGNANCY AND BREAST-FEEDING:

pregnancy:
This medicament shouldn't be used during pregnancy only if necessary.

Breast-feeding:
Breast-feeding is possible in case of short duration treatment (7days). It is unadvisable in case of prolonged treatment.

SIDE EFFECTS:

- Cutaneous manifestations: allergic eruptions, urticaria.
- General hypersensibility manifestations: fever, anaphylactic reactions.
- Digestive manifestations: stomatitis, diarrhea, nausea, vomiting, pseudomembranous colitis (rare).
- Hepatobiliary manifestations: in case of calcium salts precipitations of ceftriaxone in the biliary vesicle and the biliary ways : biliary lithiasis, biliary sludge, abnormity of the hepatic balance.
- Pancreas manifestations: exceptionally pancreatitis.
- Haematologic manifestations: acute hemolysis (rare) moderated hypereosinophilia, leuconeutropenia, thrombopenia.
- Renal manifestations: mainly in case of treatment associated with the aminoglycosides and the diuretics.
- Manifestations of central nervous system: very rare cases of headache and dizziness.
- Local manifestations: vein inflammation after intravenous injection, painful sub-cutaneous injections being able to generate necrosis.

SIGNAL TO YOUR DOCTOR OR PHARMACIST ANY BOTHERING EFFECT UNMENTIONED IN THIS ENCLOSED INSERT.

POSOLOGY AND METHOD OF ADMINISTRATION:

Posology:

- ***Adults (*CEFAXONE® 1g** and **CEFAXONE® 500mg**):

1g/day in only one injection can be increased to 2g a day in only one injection, following the infection's severity and the patient's weight.

- Lyme disease: 2g a day in one injection.

The treatment duration is usually 14 days, can be increased to 21 days in severe and late forms.

- Clinical suspicion of Purpura fulminans: the first dose to be administered if possible through intravenous way, if not through intramuscular way: 1 to 2g.
- Meningitis: 70 to 100 mg/kg/jour in 1 or 2 intravenous injections of 60 minutes.

- ***Adults (*CEFAXONE® 1g**):

- Prophylaxis of postoperative infections in surgery: intravenous or intramuscular injection of 1g in unique dose at the anesthetic induction.

- ***Children and infants:***

50 mg /kg/day in only one injection without exceeding the adult's dose.

- Lyme disease: 50 to 100 mg/kg/day in one injection.

The treatment duration is usually 14 days, can be increased to 21 days in severe or late forms.

- Clinical suspicion of Purpura fulminans: first dose to be administered if possible through intravenous way, if not through intramuscular way: 50 to 100 mg/kg, without exceeding1g.
- Meningitis: 70 to 100 mg/kg/jour in 1 or 2 intravenous injections of 60 minutes.

However, in case of meningitis for young infants aged from 3 to 12 months, an injection rythm every 12 hours is recommended because of a shorter plasmatic half-life.

- ***New-born babies:***

50 mg/kg/day in only one injection whatever the indication is.

- ***Aged subject:***

The same posology as for the adult.

- **Patients with renal failure: if the creatinine clearance ≤ 5 ml/min:**

One injection every 48 hours, without altering the posology.

Method of administration:

- Intravenous way: direct injection in 2-4 minutes or in perfusion of about 30 minutes after dilution in water for injection or in any of the following solutions for perfusion: sodium chloride at 0.9 %; sodium chloride at 0.45 % + glucose at 2.5 %; glucose at 5%; glucose at 10 %; dextran at 6 % in glucose at 5 %; hydroxyethyl starch 6-10 %.
- Sub-cutaneous way: either direct injection, the recommended minimal dilution is 2 ml for 500 mg of ceftriaxone or in sub-cutaneous perfusion of 15-30 minutes at the rate 5 ml of water for injection by each 250 mg of ceftriaxone.
- Intramuscular way: the IV forms can be used in IM way; for the IM injection, it is equally possible to reconstitute the powder with lidocaïne at the rate of 1 g /4 ml.

INCOMPATIBILITIES:

- *Premature and new-born babies:*

Some precipitations of ceftriaxone under calcium salts form have been observed with solutions for injection containing calcium.

- Infants/children/Adults :

The sodium ceftriaxone mustn't be mixed with solutions containing calcium, mainly: Ringer lactates, polyionic, plasmalytes.
The sodium ceftriaxone is incompatible with the amsacrine, the vancomycine, the fluconazole and the aminoglycosides.

PARTICULAR STORAGE CONDITIONS:

- Keep at a temperature inferior to 30°C and away from light.
- After reconstitution: the solution must be used as soon as it's reconstituted. However, it can be stored during 6 hours at a temperature inferior to 25°C.
- The colour of the reconstituted solution can vary from pale to amber yellow in the above indicated storage conditions.

LIST I

MA CEFAXONE 1 g I.V.: 909 350 1H
MA CEFAXONE 1 g I.M.: 909 350 2
MA CEFAXONE 250 mg I.M. / I.V. / S.C.: 909 350 3
MA CEFAXONE 500 mg I.M. / I.V. / S.C.: 909 350 4
MA CEFAXONE 1 g I.M. / I.V.: 909 350 5H

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

COUNCIL OF ARAB HEALTH MINISTERS

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