1. What Cefotaxime is and what it is used for

Cefotaxime is an antibiotic, i.e. a medicine which is used for the treatment of bacterial infections of:
- the lungs (pneumonia),
- skin and soft tissue,
- the urinary tract,
- the genitals (including gonorrhoea),
- the heart valves (endocarditis),
- the blood (so called ‘bacteremia’).

Furthermore cefotaxime is used to treat the Lyme disease (borreliosis, an infection primarily caused by tick bites, e.g. relapsing fever).

Cefotaxime can also be used before and during surgery in order to prevent possible infections.

2. What you need to know before you use Cefotaxime

You must not be given Cefotaxime if you:
- are allergic to Cefotaxime. If an allergic reaction occurs, you must stop taking the medicine and seek immediate medical advice.
- have ever had a severe allergic reaction to any other cephalosporin antibiotic.
- have ever had a severe allergic reaction to any other antibiotics such as penicillin, you may also be allergic to Cefotaxime.

If an allergic reaction occurs, treatment must be stopped.

If you have suffered from severe, persistent diarrhoea during or after treatment with Cefotaxime. In this case contact your doctor immediately.

If you have a widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).

If you have kidney problems.

If you experience e.g. impairment of consciousness, abnor-
mal movements and cramps after being given this medicine.

If you are on a low-salt diet.

If you have kidney problems.

If you have severe or infections that cannot be localised: 2-3 g as a single dose every 6 to 8 hours (i.e. a maximum daily dose of 12 g).

Newborns (0-28 days), infants and children up to 12 years of age

The dosage is dependent on the severity of the infection. The usual dosage for newborns, infants and children is 50 to 150 mg cefotaxime per kg body weight per day, divided into 2 to 4 single doses (i.e. every 12 to 6 hours).

Premature infants

The recommended dosage is 50 mg per kg body weight per day divided into 2 to 4 doses (every 12 to 24 hours). This maximum dose should not be exceeded due to the not yet fully matured kidneys.

Elderly

Provided that your kidney and liver function is normal, no dosage adjustment is required.

People with kidney and/or liver problems

If you have problems with your kidneys and/or liver, you may be given a lower dose. You may need to have blood tests to check that you are getting the dose you need. Your doctor will decide on the dose.

Other special recommendations

If you are pregnant or breast-feeding, think you may be preg-
nant or are planning to have a baby, ask your doctor or phar-
macist for advice before taking this medicine.

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- the lungs (pneumonia),
- skin and soft tissue,
- the urinary tract,
- the heart valves (endocarditis),
- the membranes covering the brain (meningitis),
- the abdomen,
- the blood (so called ‘bacteremia’).

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Other special recommendations

Combination

You may be given a single injection of 0.5-1 g Cefotaxime as an injection into a muscle or a vein for treatment of gonorrhoea.

Bacterial meningitis

Adults receive a daily dose of 9 to 12 g cefotaxime divided into equal doses every 6 to 8 hours.

Children receive 150 to 200 mg per kg body weight divided into equal doses every 6 to 8 hours.

Newborns (0-7 days old) and infants receive 50 mg per kg body weight every 12 hours, 7-28 days old infants every 8 hours.

Prevention of infections (perioperative prophylaxis)

You may be given between 1 g and 2 g cefotaxime before an operation for the prevention of possible infections. If the operation lasts longer than 90 minutes, you may be given an additional dose preventively.

Infections inside the abdomen

You should be given a combination of cefotaxime and an anti-
biotic acting against ‘anaerobic’ bacteria.

Your doctor will only give you cefotaxime during pregnancy after consideration of benefits and risks. Cefotaxime passes into breast milk in small amounts. Therefore it should not be used during breast-feeding.
Treatment duration

Your treatment duration depends on the severity of your infection as well as on your recovery from your illness. You will usually continue to be given the medicine for at least 2 to 3 days after you have started to recover from your illness. Treatment over at least 10 days is necessary in infections caused by the bacterium Streptococcus pyogenes.

If you are given too much Cefotaxime

Tell your doctor or nurse if you think that you have been given too much Cefotaxime.

If a dose of Cefotaxime has been forgotten

Please contact your doctor immediately. A double dose must not be given to make up for a forgotten dose. A forgotten dose should be given only if the time until the next regular dose is long enough.

If you stop using Cefotaxime

Low dosage, irregular administration or stopping treatment too early can compromise the outcome of the treatment or lead to a relapse, whose treatment is more difficult. Please follow the instructions of your doctor.

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

4. Possible side effects

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

Conditions you need to look out for

A small number of patients using Cefotaxime get an allergic reaction, potentially serious skin reaction or other side effects that require further treatment. Symptoms of these reactions include:

• Severe allergic reaction. Signs include raised and itchy rash, swelling, sometimes of the face or mouth causing difficulty in breathing.

• A widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).

• Severe, persistent diarrhoea during or after treatment with this medicine (pseudomembranous colitis).

• Superinfection: On rare occasions, medicines like Cefotaxime can cause an overgrowth of yeasts in the body which can lead to fungal infections. This side effect is more likely if you use Cefotaxime for a long time.

Very common side effects, occurring in up to 1 out of 10 treated patients:

Injection site pain following administration into a muscle.

Uncommon side effects, occurring in 1 to 10 out of 1000 treated patients:

Rash, fever, diarrhoea.

Redness of the skin, nettle rash (urticaria), itching (pruritus).

Drop or elevation of the number of certain blood cells (eosinophils, leukocytes, thrombocytes).

Increase in substances (enzymes) produced by the liver. Temporary "healing crisis" with sudden fever and shivering (jaundice, pancreatitis).

Kidney problems and increase in levels of creatinine in the blood.

Injection site pain, swelling and redness along a vein.

Other side effects of unknown frequency

Hepatotoxicity, dizziness, reduced consciousness or difficulty in thinking.

Irregular heartbeat after fast injection of the medicine.

Skin rash, which may blister (erythema multiforme).

Feeling sick (nausea), vomiting, stomach pain.

Inflammation of the liver (hepatitis), sometimes with yellowing of the skin or the white of the eyes (jaundice).

Changes in your blood cell count (granulocytosis, neutropenia), red blood cells destroyed too quickly (haemolytic anaemia).

Side effects after you are given this medicine into a muscle are possible due to the particulate that may be included for this purpose.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefotaxime

Store below 25°C. Keep the vial in the outer carton in order to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the outer carton after "EXPIR". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Cefotaxime contains

• The active substance is cefotaxime sodium.

• There are no other ingredients.

What Cefotaxime looks like and contents of the pack

Cefotaxime is available in packages with 1, 5 or 10 colourless glass vials (volume 15 ml) with a rubber stopper and a flip-off cap. Not all pack sizes may be marketed.

Marketing authorisation holder

MIP Pharma GmbH

Kirkeler Str. 41

D-66440 Blieskastel

Germany

This leaflet was last revised 23/07/2013.

The following information is intended for healthcare professionals only.

Methods of administration:

Intravenous infusion

1 g of cefotaxime should be dissolved in 40-50 ml water for injections or in another compatible fluid (e.g. 5% glucose or physiological sodium chloride solution). After preparation, the solution should be given as a 20 minute intravenous infusion.

Intramuscular injection

For intramuscular injection, 1 g cefotaxime should be dissolved in 4 ml water for injections, 2 g cefotaxime should be dissolved in 10 ml water for injections and should be injected over 3-5 minutes.

Intravenous injection

Following injection, 1 g cefotaxime should be dissolved in 4 ml water for injections, 2 g cefotaxime should be dissolved in 10 ml water for injections and should be injected over 3-5 minutes.

Intramuscular injection

The intramuscular administration is restricted to exceptional clinical situations (e.g. gonorrhea) and should undergo a benefit-risk assessment. It is recommended that not more than 4 ml are injected unilaterally. If the daily dose exceeds 2 g cefotaxime or if cefotaxime is injected more frequently than twice per day, the intravenous route is recommended.

For intramuscular administration, 1 g cefotaxime is dissolved in 4 ml of water for injections. To prevent pain from the injection, a 1% lidocaine hydrochloride solution may be used alternatively (only for adults). The solution should be administered deep into muscular injection. Solutions in lidocaine must not be administered intravenously. The product information of the chosen lidocaine containing solution must be regarded.

In the case of severe infections, intramuscular injection is not recommended.

Compatibility with intravenous liquids

The following requirements are necessary for the preparation of the solution: water for injections, 5% glucose solution and physiological sodium chloride solution.

As for all central medical products, inspect the constituted solution visually for particulate matter and discolouration prior to administration. The solution should only be used if the solution is clear and practically free from particles.

For single use only. Any remaining solution should be discarded.

Storage after reconstitution

The chemical and physical stability of the prepared solution has been demonstrated for 3 hours at 25°C and for 6 hours at 2-8°C. From a microbiological point of view, the prepared solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.