Claforan® 0.5 g

Powder and solvent for solution for injection

cefotaxime sodium

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Claforan is and what it is used for
2. Before you use Claforan
3. How to use Claforan
4. Possible side effects
5. How to store Claforan
6. Further information

1. WHAT CLAFORAN IS AND WHAT IT IS USED FOR

Pharmaceutic group
Claforan (an antibiotic from the group called cephalosporins) is a medicine used to fight bacteria.

Therapeutic indications
It is used to kill the bacteria that cause the following severe, acute and chronic infections:
- respiratory tract infections
- ear, nose and throat infections
- kidney and urinary tract infections
- skin and soft tissue infections
- bone and joint infections
- infections of the genitals, including gonorrhea
- abdominal infections (including peritonitis)
- inflammation of the membranes surrounding the brain and spinal cord (meningitis)
- blood poisoning (sepsis)
- inflammation of the inner layer of the heart (endocarditis)
- Lyme disease (particularly stage II and III) (infection mainly transmitted by tick bites) as well as in prevention of infections in a surgical context in patients with a high risk of infection.

2. BEFORE YOUR USE CLAFORAN

Contraindications
Do not use Claforan in the following situations:

- if you are allergic to cefotaxime or to one of the other ingredients of Claforan.
- if you have known allergy to another cephalosporin.
- if you have ever had an acute or severe allergic reaction to penicillins or other beta lactam antibiotics. There may be cross-reactions between penicillins and cephalosporins.

Claforan mixed with lidocaine for intramuscular injection must not be used in children under the age of 1 year.

Special precautions for use ; special warnings
Take special care with Claforan :

– if you are allergic to penicillins or other beta lactam antibiotics in any way (for contraindications in patients with known allergic reactions, see "Claforan must not be used in the following situations" above).

– if you are prone to allergic reactions (e.g. hay fever, bronchial asthma, hives) or if you have ever had allergy, you have a high risk of serious (exceptionally even fatal) allergic reactions. If you develop a feeling of tightness in your chest, or if you feel dizzy, unwell or weak, it could be a sign of such an allergic reaction (see Section 4 "Possible side effects").
If you have an allergic reaction, treatment must be stopped.

– if you notice changes in your skin or mucous membranes while using this treatment (see Section 4 "Possible side effects"), inform your doctor immediately, as Claforan can cause serious drug-induced skin reactions that require treatment.

– if you develop severe, persistent diarrhea during or up to several weeks after treatment, inform your doctor immediately, as diarrhea in its most severe form (called pseudomembranous colitis) could in certain circumstances possibly lead to death and must be treated. Do not take any medicines that inhibit bowel function.

– if you know that you have impaired kidney function, inform your doctor, so that he or she can keep this in mind when establishing the dosage, if necessary.

– if you are treated or will subsequently be treated with medicines that could be harmful to the kidneys (such as aminoglycosides), kidney function should be monitored by your doctor, as an increase in effects that could be harmful to the kidneys can occur with these kinds of medicines.

– if you are being treated with high doses, particularly if you also have impaired kidney function, this can lead to brain disturbances, along with, for example, movement disorders, seizures or consciousness disorders. Inform your doctor immediately if you have this kind of reaction.

– if your treatment lasts longer than 7 to 10 days, blood tests should be performed, as changes in the blood may occur (see Section 4 "Possible side effects").

– if you have signs of a new infection (e.g. fungal infection of the mucous membranes with redness and white deposits). Any time antibiotics are used, the number of bacteria that are resistant to the medicine being used can increase. Watch for signs of a new infection and inform your doctor if necessary.

Important information about certain other ingredients of Claforan
1 vial of Claforan 0.5 g contains approximately 1 mmol (24 mg) of sodium. You should take this into account if you need to follow a low-salt diet.

Taking other medicines

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

Other antibiotics
Using certain other antibiotics at the same time can reduce the effect of Claforan. You should therefore inform your doctor if you are taking or have recently taken another antibiotic.

Medicines that could potentially harm the kidneys and loop diuretics
Claforan can increase the harmful effects of aminoglycosides and strong diuretics (e.g. furosemide and ethacrynic acid) on the kidneys. Kidney function must be monitored when these medicines are administered at the same time as Claforan, particularly if you have impaired kidney function.

Probenecid
Administration of probenecid at the same time as Claforan can cause elevated cefotaxime concentrations in the blood, and therefore a prolonged effect. This is because probenecid slows the elimination of Claforan by the kidneys.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking/using any medicines.

Sufficient data are not available concerning use of Claforan in pregnant women.
Animal experiments have yielded no evidence that cefotaxime could have harmful effects on the fetus.
Nevertheless, Claforan should only be used during pregnancy after a careful evaluation of the benefit/risk ratio by the treating doctor, particularly during the first trimester.

Only small amounts of cefotaxime pass into breast milk. When Claforan is used during breast-feeding, intestinal flora imbalance with diarrhea, fungal infection and possibly sensitization can occur in the infant.

Driving and using machines

Based on clinical experience to date, Claforan used at low to medium doses has no effect on the ability to concentrate and react.

Very rarely, seizures, consciousness disorders, movement disorders and dizziness have been reported when high doses are used, primarily in patients who also have impaired kidney function. You should therefore not drive cars or operate machines if you notice any such side effects.

3. HOW TO USE CLAFORAN

Claforan should always be used exactly as your doctor has instructed.
The dose, method of administration and interval between injections are based on the effect of the drug on the bacteria, the severity of your infection and your general condition.
Unless your doctor prescribes otherwise, the usual dosage is as follows:

Adults and children over 12 years of age generally receive 1 to 2 g of cefotaxime every 12 hours. In severe cases, the daily dose of cefotaxime can be increased to up to 12 g. Daily doses of up to 6 g of cefotaxime can be divided into at least two separate doses administered at 12 hour intervals. Higher daily doses must be divided into at least 3 to 4 separate doses administered at 8 or 6 hour intervals.

The following table provides guidelines for dosing:

Type of infection	Single dose of cefotaxime	Dosing interval	Daily dose of cefotaxime
Typical infections suspected or shown to be caused by sensitive bacteria	1 g	12 h	2 g
Infections suspected or shown to be caused by various bacteria with high to intermediate sensitivity	2 g	12 h	4 g
Bacterial infections of unknown origin and location, and critical condition of the patient	2-3 g	8 h up to 6 h up to 4 h	6 g up to 8 g up to 12 g

To treat gonorrhea in adults, a single 0.5 g intramuscular dose of cefotaxime is to be administered. A higher dose may be necessary for bacteria that are less sensitive to the drug. Syphilis should be screened for before beginning treatment.

To prevent infections in patients having surgery, 1 to 2 g of cefotaxime should be administered 30 to 60 minutes before the beginning of the operation. The same dose can be administered repeatedly depending on the risk of infection.

To treat Lyme disease, a daily dose of 6 g of cefotaxime (for 14 to 21 days) is to be administered. The daily dose is usually administered in 3 divided doses (2 g of cefotaxime 3 times daily), but in some cases it can be administered in 2 divided doses (3 g of cefotaxime twice daily). These dosage recommendations are based on individual observations and not controlled clinical studies.

Combination treatment with orther antibiotics
Claforan in combination with aminoglycosides is indicated in serious, life-threatening infections without an antibiogram. In this case, kidney function must be monitored.
In infections caused by *Pseudomonas aeruginosa*, combination treatment with other antibiotics that are effective against *Pseudomonas* may be indicated. Combined use of Claforan with other suitable antibiotics can also be indicated to prevent infections in patients with weakened immune systems.

Infants and children up to 12 years of age receive 50 to 100 mg (up to 150 mg) of cefotaxime per kg body weight per day, depending on the severity of the infection. The daily dose is to be given as 2 or more equally divided doses, which are to be given at 12 (to 6) hour intervals. In some cases, particularly in life-threatening situations, it may be necessary to increase the daily dose to 200 mg of cefotaxime per kg body weight.

In premature infants, doses of 50 mg of cefotaxime per kg body weight per day should not be exceeded, as kidney function is not fully developed.

In patients with severely impaired kidney function (creatinine clearance of 10 ml/min or less), the initial dose (the first dose at the beginning of treatment) is to be the same as in patients with healthy kidneys. The maintenance dose is to be reduced to half the usual dose. In patients with creatinine clearance (excretion of creatinine from the blood) of 5 ml/min or less, a reduction in the maintenance dose to 1 g of cefotaxime (administered as 2 divided doses at 12 hour intervals) appears to be adequate. These recommendations are based on experience in adults.