Claforan®

Claforan powder for Solution for Injection 500mg Claforan powder for Solution for Injection 1g

Cefotaxime (as Cefotaxime Sodium) SANOFI

The following instruction is extracted from the SPC.
Technical information for the preparation and administration of cefotaxime

1. NAME OF THE MEDICINAL PRODUCT

Claforan Powder for Solution for Injection 500mg
Claforan Powder for Solution for Injection 1g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains cefotaxime sodium equivalent to 500mg cefotaxime base.
Each vial contains cefotaxime sodium equivalent to 1g cefotaxime base.
Each gram of Claforan contains approximately 48 mg (2.09 mmol) of sodium. For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for injection or infusion. A white to pale yellow-white crystalline powder.

4. CLINICAL PARTICULARS

4.2. Posology and Method of Administration

Dosage:
Claforan may be administered intravenously or by slow injection or infusion or intramuscularly.
The dosage, route and frequency of administration should be determined by the severity of infection, the sensitivity of causative organism and condition of the patient. Therapy may be initiated before the results of sensitivity tests are known.

Adults: The recommended dosage for mild to moderate infections is 1g 12 hourly. However, dosage may be varied according to the severity of the infection, sensitivity of causative organisms and condition of the patient. Therapy may be initiated before the results of sensitivity tests are known.

In severe infections dosage may be increased up to 12g daily given in 3 or 4 divided doses. For infections caused by sensitive Psuedomonas spp. daily doses of greater than 6 g will usually be required.

Dosage in Gonorrhea: A single injection of 1g may be administered intramuscularly or intravenously.

Children: The usual dosage range is 100-150mg/kg/day in 2 to 4 divided doses. However, in very severe infections doses of up to 200mg/kg/day may be required.

Neonates: The recommended dosage is 50mg/kg/day in 2 to 4 divided doses. In severe infections 150-200mg/kg/day, in divided doses, have been given.

Dosage in Renal Impairment:

In patients with a creatinine clearance less than 10 ml/minute, after an initial normal dose, the maintenance doses have to be reduced to one half of the normal dose, without change of the dose interval.

In haemodialysed patients: 1 to 2 g daily, depending on the severity of the infection; on the day of haemodialysis, cefotaxime must be administered after the dialysis session.

In patients undergoing peritoneal dialysis: 1 to 2 g daily, depending on the severity of the infection; cefotaxime is not removed by peritoneal dialysis.

ADMINISTRATION:

Intravenous and Intramuscular administration:

Intravenous administration (Injection or infusion):
Reconstitute Claforan with Water for Injection as given in the Dilution Table. Shake well until dissolved and then withdraw the entire contents of the vial into the syringe and use immediately.

Dilution Table:

Vial Size	Diluent to be added
500mg	2ml
1g	4ml

Claforan may be administered by intravenous infusion. 1-2g are dissolved in 40-100ml of Water for Injection or in the infusion fluids listed under "Pharmaceutical Particulars" in Section 6.6 Instructions for use/handling.
The prepared infusion may be administered over 20-60 minutes. To produce an infusion using vials with an infusion connector, remove the safety cap and directly connect the infusion bag. The needle in the closure will automatically pierce the vial stopper. Pressing the infusion bag will transfer solvent into the vial. Reconstitute by shaking the vial and finally, transfer the reconstituted solution back to the infusion bag ready for use.

For intermittent I.V. injections, the solution must be injected over a period of 3 to 5 minutes.

During post-marketing surveillance, potentially life-threatening arrhythmia has been reported in a very few patients who received rapid intravenous administration of cefotaxime through a central venous catheter.

Cefotaxime and aminoglycosides should not be mixed in the same syringe or infusion fluid.

Intramuscular administration:

In case of intramuscular administration, re-constitute Claforan with Water for Injection or 1% lidocaine solution as per the Dilution Table above. When using lidocaine solution as diluent, intravascular injection must be strictly avoided.

Intramuscular administration	Volume of diluent	Nature of diluent
Cefotaxime 0.50g	2 ml	water for injection or 1 % lidocaine solution
Cefotaxime 1g	4 ml	

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

None.

6.2. Incompatibilities

Prolonged use of an anti-infective may result in the development of superinfection due to organisms resistant to that anti-infective. Aminoglycosides are incompatible with cephalosporins in parenteral mixtures.

6.3. Shelf Life

Unopened: 2 years. Reconstituted solution: See Section 6.4 and 6.6.

6.4. Special Precautions for Storage

Unopened: Do not store above 25°C. Keep the vial in the outer carton.
Injection: Use immediately after reconstitution.
Infusion: Some reconstituted or mixed solutions will retain satisfactory potency for up to 24 hours refrigerated (at 2-8^{0}C) – see Section 6.6 for further information.
After 24 hours any unused solution should be discarded. From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 - 8^{0}C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6.5. Nature and Contents of Container

Claforan is supplied in type III colourless glass vials, closed with a grey elastomer stopper and sealed with either an aluminium cap fitted with a detachable flip top, or an infusion connector closure.
The bottles are boxed individually and in packs of 10, 25 or 50.
Not all pack sizes may be marketed.

6.6. Instructions for use/handling
Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any unused contents.
When dissolved in Water for Injections, a straw-coloured solution is formed which is suitable for intravenous or intramuscular injection.
Reconstituted Solution: Whilst it is preferable to use only freshly prepared solutions for both intravenous and intramuscular injection, Claforan is compatible with several commonly used intravenous infusion fluids and will retain satisfactory potency for up to 24 hours refrigerated (2-8°C) in the following:
Water for Injections
Sodium Chloride Injection
5% Dextrose Injection
Dextrose and Sodium Chloride Injection
Compound Sodium Lactate Injection
(Ringer-lactate Injection)

Claforan is also compatible with 1% lidocaine, however freshly prepared solutions should be used.
Claforan is also compatible with metronidazole infusion (500mg/100ml) and both will maintain potency when refrigerated (2-8°C) for up to 24 hours.
Some increase in colour of prepared solutions may occur on storage. However, provided the recommended storage conditions are observed, this does not indicate change in potency or safety.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 13th May 1981
Date of last renewal: 18th December 2009

10. DATE OF (PARTIAL) REVISION OF THE TEXT

April 2019

PACKAGE LEAFLET: INFORMATION FOR THE USER

Claforan®

Claforan powder for Solution for Injection 500mg Claforan powder for Solution for Injection 1g

Cefotaxime (as Cefotaxime Sodium) SANOFI

Is this leaflet hard to see or read?
Phone 01 403 5600 for help

Read all of this leaflet carefully before you start treatment with this medicine
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Claforan is and what it is used for

The name of your medicine is Claforan Powder for Solution for Injection 500mg or Claforan Powder for Solution for Injection 1g (called Claforan throughout this leaflet). Claforan contains a medicine called Cefotaxime. This belongs to a group of medicines called antibiotics. It works by killing the bacteria that cause infections.

Claforan is used for infections of the:

- Respiratory tract such as chest and lungs
- Bladder and urethra (the tube which carries urine from the bladder)
- Blood - sometimes called 'septicaemia'
- Skin and underneath the skin, including muscle – sometimes called "soft tissue"
- Joints and bones – including your hips and knees
- Genital tract in women - including infections of the uterus, fallopian tubes and ovaries that can happen pre, post and during pregnancy
- Gonorrhoea - a type of sexually transmitted disease

It can also be used to treat other infections, such as meningitis.

It can also be used before some operations, to stop an infection happening.

2. Before you have Claforan

Do not have Claforan if:
X You are allergic (hypersensitive) to Claforan or any of the other ingredients of Claforan (see Section 6: Further Information).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
X You are allergic to cephalosporins
X Claforan is sometimes mixed with lidocaine. In this case do not have this injection if:
. You are allergic to lidocaine or other local anaesthetics
. Your child is younger than 30 months
. You have heart disease, problems with your heartbeat or severe heart failure

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before having Claforan.

Take Special Care with Claforan
Check with your doctor or nurse before having this medicine if:
▲ You are allergic to any antibiotics, particularly an antibiotic called penicillin
▲ You have kidney problems
▲ You are on a sodium controlled diet
▲ You have ever had severe diarrhoea after taking some antibiotics ('Pseudomembranous colitis'). If you experience severe diarrhoea, you should contact your doctor straight away as you may need urgent medical attention.

Taking other medicines
Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Claforan can affect the way some other medicines work. Also some medicines can affect the way Claforan works.

In particular, check with your doctor if you are taking any of the following:
- Aminoglycoside antibiotics - including gentamicin, streptomicin, neomycin, kanamycin, amikacin or tobramycin
- Water tablets (diuretics) such as furosemide, etacrynic acid
- Probenecid – used for gout

Tests
If you require any tests (such as blood, urine or diagnostic), while taking this medicine, please make sure your doctor knows that you are taking Claforan.

Pregnancy and breast-feeding
Talk to your doctor or nurse before you are given Claforan if you are pregnant, might become pregnant or are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.
Driving and using machines
You may start to move abnormally, suffer from sudden involuntary muscle contractions, dizziness or feel less alert. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Claforan
This medicinal product contains 48 mg of sodium per gram of Claforan. This may be harmful to people on a low sodium or low salt diet.

3. How to have Claforan

How Claforan is given
- Your medicine will normally be given to you by a doctor or nurse
- It will be given by injection into a vein or muscle
- It can also be given as an infusion through a drip into a vein

How much Claforan is given
- Your doctor will decide on how much Claforan to give you
- The dose will depend on the type of infection and any other illnesses you may have
- You may be given a different dose depending on your weight
- The dosage and frequency of your treatment will depend on your infection
- If you have any kidney problems you may be given a lower dose of Claforan.

The usual dose is:
Adults (18 years and over)
Mild to Moderate infection:
- 1g every 12 hours

Severe infection:
- Up to 12g each day

Children
Mild to Moderate infection:
- 100-150mg for every kilogram of body weight
- This is given once a day in 2 to 4 divided doses

Severe infection:
- Up to 200mg for every kilogram of body weight once a day

Babies
Mild to Moderate infection:
- The usual dose of Claforan is 50mg for every kilogram of body weight
- This is given once a day in 2 to 4 divided doses

Severe infection:
- 150-200mg for every kilogram of body weight once a day and in divided doses
- This has been given once a day in divided doses

If you have more Claforan than you should
It is unlikely that your doctor or nurse will give you too much medicine.
Your doctor and nurse will be checking your progress, and checking the medicine that you are given. Ask them if you are not sure why you are getting a dose of medicine.
If you miss a dose of Claforan
Your doctor or nurse will have instructions about when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose, then talk to your doctor or nurse.
If you stop having Claforan
It is important that the course of treatment your doctor has prescribed is finished. Do not stop having Claforan just because you feel better.

4. Possible side effects

Like all medicines, Claforan can cause side effects, although not everybody gets them. These side effects are usually mild and last for a short time.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment if:
- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- You have blistering of the skin, mouth, eyes or genitals. This may be something called 'Stevens-Johnson syndrome' or 'Toxic Epidermal Necrolysis' or Acute generalised exanthematous pustulosis (AGEP)
- You have sudden involuntary muscle contractions or begin to lose consciousness. This is called "encephalopathy"
- You feel your heart flutter
- Severe watery diarrhoea, possibly with blood and mucus ('Pseudomembranous colitis')
- you notice changes in the way your kidneys are working

Tell your doctor or nurse if any of the following side effects get serious or lasts longer than a few days:
- You bruise more easily and get more infections than usual. This could be because of a blood disorder.
- Reactions at the site of the injection including reddening of the skin, pain or swelling
- Feeling or being sick (vomiting), diarrhoea
- Feeling tired or unwell
- Dizziness or headache
- Liver problems such as jaundice or hepatitis that may cause your eyes or skin to go yellow and your urine to become darker.
- Fits
- Irregular heartbeat (palpitations)
- Difficulty breathing, wheezing, tightness in the chest (something called "bronchospasm")
- Skin rash
- Blood in your urine. This could be due to a kidney problem (called interstitial nephritis)
- Fever
- Infection

Other side effects include:
- Blood and kidney problems or changes in the way your kidney works.

These would show up in the results of blood tests.
- A Jarisch-Herxheimer reaction that may cause skin rash, itching, fever, blood and liver problems, difficulty in breathing and joint discomfort.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Claforan

- Keep out of the sight and reach of children
- Do not use Claforan after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month
- Vials of Claforan powder must not be stored above 25°C
- After being mixed with water for injections (reconstituted), vials of Claforan should be used within 24 hours
- Once reconstituted, Claforan can be stored in the fridge for up to 24 hours
- If the reconstituted solution is not used within 24 hours, the unused solution should be discarded.
- Claforan can also be mixed with 1 percent lidocaine and should be used straight away.

6. Further Information

What Claforan contains
- The active substance is cefotaxime
- There are no other ingredients.

What Claforan looks like and contents of the pack
- Claforan is a white to pale yellow-white crystalline powder and each vial contains 500mg or 1g of cefotaxime
- The vials are boxes in packs of 1, 10, 25 or 50. Not all pack size may be marketed.
- Claforan powder will be mixed with the water for injections to make a straw-coloured solution which is ready for use as an injection or an infusion (a drip)

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Claforan is:
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