Claforan Injection
Cefotaxime Sodium

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT
Claforan Injection 250mg, 500mg, 1g and 2g.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
250mg vial: Contains Cefotaxime Sodium equivalent to 250mg cefotaxime base.
500mg vial: Contains Cefotaxime Sodium equivalent to 500mg cefotaxime base.
1g vial: Contains Cefotaxime Sodium equivalent to 1g cefotaxime base.
2g vial: Contains Cefotaxime Sodium equivalent to 2g cefotaxime base.
Each gram of Claforan contains approximately 48mg (2.09mmol) of sodium.

3. PHARMACEUTICAL FORM
Vials containing powder for injection or infusion.
Claforan is supplied as a white to slightly creamy powder, which when dissolved in Water for Injections forms a straw-coloured solution suitable for IV or IM injection. Variations in the intensity of colour of the freshly prepared solution do not indicate a change in potency or safety.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications
Properties: Claforan is a broad-spectrum bactericidal cephalosporin antibiotic. Claforan is exceptionally active in vitro against Gram-negative organisms sensitive or resistant to first or second generation cephalosporins. It is similar to other cephalosporins in activity against Gram-positive organisms.
Indication: Claforan is indicated in the treatment of the following infections either before the infecting organism has been identified or when caused by bacteria of established sensitivity.

Septicaemias.
Respiratory Tract Infections such as acute and chronic bronchitis, bacterial pneumonia, infected bronchiectasis, lung abscess and post-operative chest infections.
Urinary Tract Infections such as acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.
Soft-tissue Infections such as cellulitis, peritonitis and wound infections.
Bone and Joint Infections such as osteomyelitis, septic arthritis.
Obstetric and Gynaecological Infections such as pelvic inflammatory disease.
Gonorrhoea particularly when penicillin has failed or is unsuitable.
Other Bacterial Infections meningitis and other sensitive infections suitable for parenteral antibiotic therapy.

PROPHYLAXIS: The administration of Claforan prophylactically may reduce the incidence of certain post-operative infections in patients undergoing surgical procedures that are classified as contaminated or potentially contaminated or in clean operations where infection would have serious effects.
Protection is best ensured by achieving adequate local tissue concentrations at the time contamination is likely to occur. Claforan should therefore be administered immediately prior to surgery and if necessary continued in the immediate post-operative period.
Administration should usually be stopped within 24 hours since continuing use of any antibiotic in the majority of surgical procedures does not reduce the incidence of subsequent infection.

BACTERIOLOGY: The following organisms have shown in vitro sensitivity to Claforan.
GRAM POSITIVE:
Staphylococci, including coagulase-positive, coagulase-negative and penicillinase-producing strains.
Beta-haemolytic and other streptococci such as Streptococcus mitis (viridans) (many strains of enterococci, eg. Streptococcus faecalis, are relatively resistant).
Streptococcus (Diplococcus) pneumonia.
Clostridium spp.

GRAM NEGATIVE:
Escherichia coli.
Haemophilus influenzae including ampicillin resistant strains.
Klebsiella spp.
Proteus spp. (both indole positive and indole negative).
Enterobacter spp.
Neisseria spp. (including β-lactamase producing strains of N. gonorrhoea).
Salmonella spp. (including Sal. typhi).
Shigella spp.
Providencia spp.
Serratia spp.
Citrobacter spp.

Claforan has frequently exhibited useful in vitro activity against Pseudomonas and Bacteroides species although some strains of Bacteroides fragilis are resistant.
There is in vitro evidence of synergy between Claforan and aminoglycoside antibiotics such as gentamicin against some species of Gram-negative bacteria including some strains of Pseudomonas. No in vitro antagonism has been noted. In severe infections caused by Pseudomonas spp. the addition of an aminoglycoside antibiotic may be indicated.

4.2. Posology and Method of Administration
DOSAGE.
Claforan may be administered intravenously, by bolus injection, by infusion or intramuscularly. The dosage, route and frequency of administration should be determined by the severity of infection, the sensitivity of causative organisms 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 Pseudomonas spp. daily doses of greater than 6g will usually be required.

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 Gonorrhoea: A single injection of 1g may be administered intramuscularly or intravenously.

Dosage in Renal Impairment: Because of extra-renal elimination, it is only necessary to reduce the dosage of Claforan in severe renal failure (GFR < 5ml/min = serum creatinine approximately 751 micromol/l). After an initial loading dose of 1g, daily dose should be halved without change in the frequency of dosing, ie. 1g in 12 hourly becomes 0.5g 12 hourly, 1g 8 hourly becomes 0.5g
8 hourly, 2g 8 hourly becomes 1g 8 hourly etc. As in all other patients, dosage may require further adjustment according to the course of the infection and the general condition of the patient.

ADMINISTRATION:

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

**Intravenous and Intramuscular Administration:** 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:

<table>
<thead>
<tr>
<th>Vial Size</th>
<th>Diluent to be added</th>
</tr>
</thead>
<tbody>
<tr>
<td>250mg</td>
<td>2ml</td>
</tr>
<tr>
<td>500mg</td>
<td>2ml</td>
</tr>
<tr>
<td>1g</td>
<td>4ml</td>
</tr>
<tr>
<td>2g</td>
<td>10ml</td>
</tr>
</tbody>
</table>

**Intravenous Infusion:** 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’. 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.

**Intravenous administration (injection or infusion):**

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.

4.3. Contra-indications

- Hypersensitivity to cephalosporins.
- In patients with a history of hypersensitivity to Cefotaxime and/or to any component of Claforan.

Allergic cross reactions can exist between penicillins and cephalosporins (see section 4.4)

For pharmaceutical forms containing lidocaine:
- known history of hypersensitivity to lidocaine or other local anesthetics of the amide type
- non-paced heart block
- severe heart failure
- administration by the intravenous route
- infants aged less than 30 months of age
4.4. Special Warnings and Precautions for Use

As with other antibiotics, the use of cefotaxime, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient’s condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

- Anaphalactic reactions

Serious, including fatal hypersensitivity reactions have been reported in patients receiving cefotaxime (see sections 4.3 and 4.8).

If a hypersensitivity reaction occurs, treatment must be stopped.

The use of cefotaxime is strictly contra-indicated in subjects with a previous history of immediate-type hypersensitivity to cephalosporins.

Since cross allergy exists between penicillins and cephalosporins, use of the latter should be undertaken with extreme caution in penicillin sensitive subjects.

- Serious bullous reactions

Cases of serious bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with cefotaxime (see section 4.8). Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/or mucosal reactions occur.

- Clostridium difficile associated disease (e.g. pseudomembranous colitis)

Diarrhea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment, may be symptomatic of Clostridium difficile associated disease (CDAD). CDAD may range in severity from mild to life threatening, the most severe form of which is pseudo-membranous colitis.

The diagnosis of this rare but possibly fatal condition can be confirmed by endoscopy and/or histology.

It is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of cefotaxime.

If a diagnosis of pseudomembranous colitis is suspected, cefotaxime should be stopped immediately and appropriate specific antibiotic therapy should be started without delay.

*Clostridium difficile* associated disease can be favoured by faecal stasis.

Medicinal products that inhibit peristalsis should not be given.

- Blood disorders

Leukopenia, neutropenia and, more rarely, bone marrow failure, pancytopenia, or agranulocytosis may develop during treatment with cefotaxime (see Section 4.8.). For courses of treatment lasting longer than 10 days, blood counts should therefore be monitored and treatment discontinuation should be considered in case of abnormal results.
Some cases of eosinophilia and thrombocytopenia, rapidly reversible on stopping treatment, have been reported. Cases of haemolytic anemia have also been reported. (see section 4.8)

- Patients with renal insufficiency

The dosage should be modified according to the creatinine clearance calculated (see section 4.2). Caution should be exercised if cefotaxime is administered together with aminoglycosides; probenecid or other nephrotoxic drugs (see section 4.5). Renal function must be monitored in these patients, the elderly, and those with pre-existing renal impairment.

- Neurotoxicity

High doses of beta-lactam antibiotics, including cefotaxime, particularly in patients with renal insufficiency, may result in encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (see section 4.8). Patients should be advised to contact their doctor immediately prior to continuing treatment if such reactions occur.

- Precautions for administration

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. The recommended time for injection or infusion should be followed (see section 4.2).

See section 4.3 for contraindications for formulations containing lidocaine.

- Effects on Laboratory Tests

As with other cephalosporins a positive Coombs' test has been found in some patients treated with cefotaxime. This phenomenon can interfere with the cross-matching of blood.

Urinary glucose testing with non-specific reducing agents may yield false-positive results. This phenomenon is not seen when a glucose-oxydase specific method is used.

- Sodium intake

The sodium content of cefotaxime sodium (48.2 mg/g) should be taken into account.

4.5. Interactions with other Medicaments and other forms of Interaction

Uricosurics: Probenecid interferes with the renal tubular transfer of cefotaxime, thereby increasing cefotaxime exposure about 2-fold and reducing renal clearance to about half at therapeutic doses. Due to the large therapeutic index of cefotaxime, no dosage adjustment is needed in patients with normal renal function. Dosage adjustment may be needed in patients with renal impairment (see sections 4.4 and 4.2).
Aminoglycoside antibiotics and diuretics: As with other cephalosporins, cefotaxime may potentiate the nephrotoxic effects of nephrotoxic drugs such as aminoglycosides or potent diuretics (e.g. furosemide). Renal function must be monitored in these patients (see section 4.4).

**Interference with Laboratory Tests:** A positive Coombs test may be seen during treatment with cephalosporins. This phenomenon may occur during treatment with cefotaxime. A false positive reaction to glucose may occur with reducing substances but not with the use of specific glucose oxidase methods.

### 4.6. Pregnancy and Lactation

**Pregnancy:**
The safety of cefotaxime has not been established in human pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. They are, however, no adequate and well controlled studies in pregnant women.

Cefotaxime crosses the placental barrier. Therefore, cefotaxime should not be used during pregnancy unless the anticipated benefit outweighs any potential risks.

**Lactation:**

Cefotaxime passes into human breast milk.

Effects on the physiological intestinal flora of the breast-fed infant leading to diarrhoea, colonisation by yeast-like fungi, and sensitisation of the infant cannot be excluded.

Therefore, a decision must be made whether to discontinue breast-feeding or to discontinue therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

### 4.7. Effects on Ability to Drive and Use Machines

High doses of cefotaxime, particularly in patients with renal insufficiency, may cause encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (see section 4.8). In the case of side effects such as dizziness the patient's ability to concentrate and to react properly may be impaired. In such cases patients should refrain from driving cars and using machines.

### 4.8. Undesirable Effects

<table>
<thead>
<tr>
<th>System organ class</th>
<th>Very Common (≥1/10)</th>
<th>Common (≥1/100 to &lt;1/10)</th>
<th>Uncommon (≥1/1,000 to &lt;1/100)</th>
<th>Rare (≥1/10,000 to &lt;1/1,000)</th>
<th>Very rare (&lt;1/10,000)</th>
<th>Not known (cannot be estimated from available data)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Superinfection (see section 4.4)</td>
</tr>
<tr>
<td>Blood and</td>
<td></td>
<td></td>
<td>Leukopenia</td>
<td></td>
<td></td>
<td>Bone marrow</td>
</tr>
</tbody>
</table>

Reference: 20730 1.3.1.3 - Leaflet Text - NM - 100% w/w – 2016-12-04 CCDS V4 Clean Text
<p>| the lymphatic system disorders | Eosinophilia Thrombocytopenia | failure Pancytopenia Neutropenia Agranulocytosis (see section 4.4) Haemolytic anaemia |
| Immune system disorders | Jarisch-Herxheimer reaction | Anaphylactic reactions Angioedema Bronchospasm Anaphylactic shock |
| Nervous system disorders | Convulsions (see section 4.4) | Headache Dizziness Encephalopathy (e.g. impairment of consciousness, abnormal movements) (see section 4.4) |
| Cardiac disorders | | Arrhythmia following rapid bolus infusion through central venous catheter |
| Gastrointestinal disorders | Diarrhea | Nausea Vomiting Abdominal pain Pseudomembranous colitis (see section 4.4) Candidiasis |
| Hepatobiliary disorders | Increase in liver enzymes (ALAT, ASAT, LDH, gamma-GT and/or | Hepatitis* (sometimes with jaundice) |</p>
<table>
<thead>
<tr>
<th></th>
<th>alkaline phosphatase and/or bilirubin</th>
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</thead>
<tbody>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td>Rash Pruritus Urticaria</td>
<td>Erythema multiforme Stevens-Johnson syndrome Toxic epidermal necrolysis (see section 4.4) Acute generalized exanthematous pustulosis (AGEP)</td>
<td></td>
</tr>
<tr>
<td><strong>Renal and Urinary disorders</strong></td>
<td>Decrease in renal function/increase of creatinine (particularly when co-prescribed with aminoglycosides)</td>
<td>Acute renal failure (see Section 4.4) Interstitial nephritis</td>
<td></td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td><em>For IM formulations:</em> Pain at the injection site</td>
<td>Fever Inflammatory reactions at the injection site, including phlebitis/thrombophlebitis</td>
<td><em>For IM formulations (since the solvent contains lidocaine):</em> Systemic reactions to lidocaine</td>
</tr>
</tbody>
</table>

*postmarketing experience

Jarisch-Herxheimer reaction

For the treatment of borreliosis (Lyme’s Disease), a Jarisch-Herxheimer reaction may develop during the first days of treatment.
The occurrence of one or more of the following symptoms has been reported after several week's treatment of borreliosis: skin rash, itching, fever, leucopenia, increase in liver enzymes, difficulty of breathing, joint discomfort.

Hepatobiliary disorders

Increase in liver enzymes (ALAT, ASAT, LDH, gamma-GT and/or alkaline phosphatase) and/or bilirubin have been observed. These laboratory abnormalities may rarely exceed twice the upper limit of the normal range and elicit a pattern of liver injury, usually cholestatic and most often asymptomatic.

**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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**4.9. Overdose**

Symptoms of overdose may largely correspond to the profile of side effects.

There is a risk of reversible encephalopathy in cases of administration of high doses of β-lactam antibiotics including cefotaxime.

In case of overdose, cefotaxime must be discontinued, and supportive treatment initiated, which includes measures to accelerate elimination, and symptomatic treatment of adverse reactions (e.g. convulsions).

No specific antidote exists. Serum levels of cefotaxime can be reduced by haemodialysis or peritoneal dialysis.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1. Pharmacodynamic Properties**

Claforan is a broad spectrum bactericidal cephalosporin antibiotic. Claforan is exceptionally active in vitro against Gram-negative organisms sensitive or resistant to first or second generation cephalosporins. It is similar to other cephalosporins in activity against Grampositive bacteria.

**5.2. Pharmacokinetic Properties**

Table 1

Pharmacokinetics in adults
1. **Dose**
   - healthy adults
     - i.v. (5 min)
       - 1g
   - healthy adults
     - i.m.
       - 1g

2. **Absorption**
   - Bioavailability in %
     - 100
     - 90-95

3. **Kinetic parameters**
   - Tmax (h)
     - 0.9 – 1.1
   - Cmax (µg/ml)
     - 100
     - 20-30
   - Terminal half-life (h)
     - 0.5
     - 1.3
   - Volume of distribution (liters/kg)
     - 0.30

4. **Protein binding**
   - Type: Albumin
   - %: 25-40

5. **Metabolism**
   - Liver
   - Kidney
   - Other tissues %
     - Product
     - Metabolites
     - Desacetyl CTX*
     - Lactamine form
     - Lactamine form
   - M1
   - M2
   - M3

6. **Excretion**
   - Urine
     - Faeces %
     - 90%
     - CTX: 50%
     - desacetyl CTX: 15-25%
     - M2 + M3: 15-30%
     - 10%

*The half-life of desacetylcefotaxime in healthy subjects is approximatively 2h. Its antibacterial activity is synergistic with that of cefotaxime.

After a 1000mg intravenous bolus, mean peak plasma concentrations of cefotaxime usually range between 81 and 102 g/ml. Doses of 500mg and 2000mg produce plasma concentrations of 38 and 200 g/ml, respectively. There is no accumulation following administration of 1000mg intravenously or 500mg intramuscularly for 10 or 14 days.

The apparent volume of distribution at steady-state of cefotaxime is 21.6L/1.73m² after 1g intravenous 30 minute infusion.

Concentrations of cefotaxime (usually determined by non-selective assay) have been studied in a wide range of human body tissues and fluids. Cerebrospinal fluid concentrations are low when the meninges are not inflamed, but are between 3 and 30 g/ml in children with meningitis. Cefotaxime usually passes the blood-brain barrier in levels above the MIC of common sensitive pathogens when the meninges are inflamed. Concentrations (0.2-5.4 g/ml), inhibitory for most Gram-negative bacteria, are attained in purulent sputum, bronchial secretions and pleural fluid after doses of 1 or 2g. Concentrations likely to be effective against most sensitive organisms are similarly attained in female reproductive organs.
organs, otitis media effusions, prostatic tissue, interstitial fluid, renal tissue, peritoneal fluid and gall bladder wall, after usual therapeutic doses. High concentrations of cefotaxime and desacetyl-cefotaxime are attained in bile. Cefotaxime is partially metabolised prior to excretion. The principal metabolite is the microbiologically active product, desacetyl-cefotaxime. Most of a dose of cefotaxime is excreted in the urine about 60% as unchanged drug and a further 24% as desacetyl-cefotaxime. Plasma clearance is reported to be between 260 and 390ml/minute and renal clearance 145 to 217ml/minute. After intravenous administration of cefotaxime to healthy adults, the elimination half-life of the parent compound is 0.9 to 1.14 hours and that of the desacetyl metabolite, about 1.3 hours. In neonates the pharmacokinetics are influenced by gestational and chronological age, the half-life being prolonged in premature and low birth weight neonates of the same age. In severe renal dysfunction the elimination half-life of cefotaxime itself is increased minimally to about 2.5 hours, whereas that of desacetyl-cefotaxime is increased to about 10 hours. Total urinary recovery of cefotaxime and its principal metabolite decreases with reduction in renal function.

5.3. Preclinical Safety Data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients
None.

6.2. Incompatibilities
None stated.

6.3. Shelf Life
Finished Product: 24 months.
Reconstituted Solution: 24 hours.

6.4. Special Precautions for Storage
Finished Product: Store below 25°C. Protect from light.
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 Chlorides Injection.
Compound Sodium Lactate Injection. (Ringer-lactate Injection)
After 24 hours any unused solution should be discarded. 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.
6.5. Nature and Contents of Container
Claforan is supplied in tubular or moulded 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.

6.6. Instruction for Use/Handling
Not applicable.

7. MARKETING AUTHORISATION HOLDER
Aventis Pharma Limited,
50 Kings Hill Avenue
West Malling
Kent
ME19 4AH
United Kingdom
Or Trading as
Sanofi-aventis
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

8. MARKETING AUTHORISATION NUMBER
PL 04425/0188

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
31 October 2002.

10. DATE OF ISSUE OF THE TEXT

PATIENT INFORMATION LEAFLET

CLAFORAN INJECTION (cefotaxime sodium)

Please read this leaflet carefully before the doctor or nurse starts to give you this medicine.
If you are the parent of a child who is to be given this medicine, you should read this leaflet carefully replacing ‘you’ with ‘your child’ throughout and tell the doctor or nurse if you have any questions about any information in the leaflet.
If you do not understand it or you want to know more, ask your doctor or pharmacist. Keep the leaflet, you may want to read it again.
This leaflet is a summary. It does not contain the complete information about your medicine.
If you have any further questions or are not sure about anything, ask your doctor, nurse or pharmacist who have access to additional information.

WHAT IS IN YOUR MEDICINE?
The name of your medicine is Claforan. It is a powder which has been mixed with liquid, normally Water for Injection, to make a solution which is ready for use as an injection or an infusion (a ‘drip’).

Claforan is available in vials. These vials contain cefotaxime sodium equivalent to either 0.25g, 0.5g, 1g or 2g of cefotaxime. There are no other ingredients.

Claforan may be packed as individual vials or boxes of 10 vials.

The injection solution also contains Water for Injection.

Cefotaxime sodium, the active ingredient, belongs to a group of medicines called antibiotics. Antibiotics kill bacteria which cause infections in your body.

WHO HAS MADE YOUR MEDICINE?
The company responsible (also known as the Marketing Authorisation Holder) for this product is: Sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

It is manufactured by Patheon UK Limited, Covingham, Swindon, Wiltshire, UK.

WHAT IS YOUR MEDICINE USED FOR?
Your medicine is used to treat bacterial infections including those of the chest (respiratory tract infections), the bladder and urethra (the tube which carries urine from the bladder), the blood (septicaemia), skin and tissues, bone and joints and genital tract in women, including infections which occur, pre, post and during pregnancy. Claforan is also active against a type of sexually transmitted disease called gonorrhoea. Claforan can also be used to treat other infections, such as meningitis.

Claforan may be given to you prior to surgery to reduce the incidence of post operative infections.

WILL THE MEDICINE SUIT YOU?
Before you are given Claforan, please read the following statements.
- Have you ever suffered a reaction to Cefotaxime or to any components of Claforan.
- Have you ever suffered a severe reaction to cephalosporin antibiotics, or any other antibiotics, particularly penicillins?
- Are you pregnant or breast feeding?
- Are you on a sodium controlled diet?
- Have you ever had colitis?
- Do you suffer from kidney problems?

If you think that any of the statements apply to you, DO NOT have the injection or drip – discuss the situation with your nurse or doctor before you are given your medicine.

The injection solution may contain other ingredients, such as lidocaine. If you are allergic to lidocaine, your child is younger than 30 months or you suffer from either heart failure or an unpaced heart block, you must discuss the situation with the nurse or doctor before you are given your medicine. The infusion solution may also contain other ingredients depending on the liquid used in your drip prescribed by your doctor. You should ask the person giving you the drip what it contains in case you may be allergic to any of these ingredients.

If you are the parent of a child who is to receive Claforan, if you know that they have ever suffered a severe reaction to this or any other antibiotics, particularly penicillins, then you should discuss the situation with the nurse or doctor before the medicine is given.

If you are taking Cefotaxime together with aminoglycosides, renal function monitoring must be performed by your doctor.

If your treatment lasts longer than 10 days, blood tests should be performed by your doctor. The treatment should be stopped in the event of neutropenia, leukopenia (decrease in white blood cells) or other blood disorders such as pancytopenia, agranulocytosis or bone marrow failure.

ARE YOU TAKING ANY OTHER MEDICINES?
Claforan may interfere with other medicines that you may be taking, such as diuretics (used to increase the flow of urine), probenecid and aminoglycoside antibiotics (used to treat infections). In some cases your doctor will arrange further monitoring, but this is routine and nothing to worry about.

It is important that you tell your doctor, nurse or pharmacist about ALL the medicines that you are taking including those bought without a prescription. If you require any tests, blood, urine or diagnostic, whilst taking this medicine please ensure the doctor or nurse knows that you are taking Claforan.

**HOW SHOULD YOU TAKE YOUR MEDICINE?**

This medicine will always be given to you by a doctor or nurse. This is because it needs to be given either as an injection or by a drip. In adults, Claforan will normally be given twice daily, however in children and neonates Claforan is normally given in 2-4 divided doses.

If Claforan is used as an injection it should be diluted as the following:
- 250mg of cefotaxime as cefotaxime sodium, the active ingredient, in 2mI of solution for injection into a vein or muscle.
- 500mg of cefotaxime as cefotaxime sodium, the active ingredient, in 2mI of solution for injection into a vein or muscle.
- 1g of cefotaxime as cefotaxime sodium, the active ingredient, in 4ml of solution for injection into a vein or muscle.
- 2g of cefotaxime as cefotaxime sodium the active ingredient, in 10ml of solution for injection into a vein or muscle.

If Claforan is used as an infusion it contains a concentration of 1–2g of cefotaxime as cefotaxime sodium, the active ingredient, in 40–100ml of solution.

Your doctor will have prescribed the dose of the medicine which is correct for you, depending on the type of infection and any other illnesses you may have. If you ask the person giving you the medicine they will tell you how much and how often you have been prescribed it by your doctor.

**WHAT IF YOU TAKE TOO MUCH?**

It is most unlikely that you will be given too much medicine by the nurse or doctor. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. Always ask if you are not sure why you are getting a dose of medicine.

**WHAT IF YOU MISS A DOSE?**

Your doctor or nurse have instructions when to give you your medicine. It is most 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 nurse or doctor. It is important that the course of treatment your doctor has prescribed is taken. You may start to feel better but it is important not to stop taking this medicine, until the doctor advises, otherwise your condition may get worse again.

**WHAT ABOUT SIDE EFFECTS?**

You may develop a skin rash or itchy skin, a fever, thrush, a furry tongue, kidney problems which may cause pain in your kidney region, tummy upsets, slight sickness or diarrhoea. If the diarrhoea gets very bad, Claforan treatment should be stopped and other medicines will be given to you to stop the diarrhoea. You may also develop weakness, shortness of breath, lethargy, and confusion: these can be signs of acute renal failure.

You may also develop a skin rash associated with fever. Rarely, you may develop a headache, or feel that your head hurts. You should mention this to your doctor or nurse as they may need to give you more treatment for this. You may also feel dizzy.
People may sometimes develop severe allergic reactions, such as breathing difficulties which will require treatment immediately or swelling of the neck, face or throat. If you experience this you should call a doctor or nurse urgently.
If you suffer from a severe rash with or without lesions around the mouth, contact a doctor immediately.
Claforan may sometimes affect your blood, although this is very unusual. It may cause you to feel tired or generally unwell. If you take the medicine for more than 10 days, your doctor may ask you to take a blood test, but this is just routine and nothing to worry about.
If Claforan is given as an injection some people find it slightly painful where the injection has been given. Claforan may also cause your veins to swell following intravenous injection. Claforan may cause injury to your liver, this may make you feel tired or unwell. You may also have fever and yellowing of the skin or yellowing of the whites of your eyes.
If you feel your heart flutter, contact your doctor immediately.
If you start to move abnormally, suffer from sudden, involuntary muscle contractions or you begin to lose consciousness, you must call a doctor urgently. These are symptoms of encephalopathy.
If you think you are reacting badly in any of these or any other ways to your medicine, talk to your nurse or doctor straight away.

**Reporting of side effects**
**United Kingdom**
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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
By reporting side effects you can help provide more information on the safety of this medicine.

**HOW SHOULD YOU STORE YOUR MEDICINE**
You will not be asked to store your medicine. It will be brought to your bed ready to be given to you straight away.
Claforan vials must be stored below 25ºC, protected from light. They should not be used past the expiry date on the label. Claforan can be stored in a fridge for up to 24 hours, once reconstituted. This leaflet was revised in December 2016.