PACKAGE LEAFLET: INFORMATION FOR THE USER
Cefotaxime 500 mg powder for solution for injection
Cefotaxime 1 g powder for solution for injection or infusion
Cefotaxime

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cefotaxime Injection is and what it is used for
2. What you need to know before you use Cefotaxime Injection
3. How to use Cefotaxime Injection
4. Possible side effects
5. How to store Cefotaxime Injection
6. Contents of the pack and other information

1. WHAT CEFOTAXIME INJECTION IS AND WHAT IT IS USED FOR

Cefotaxime Injection is an antibiotic belonging to a group called "cephalosporins". It is generally effective to fight a range of micro-organism. It is used for the treatment of a range of serious bacterial infections of:
- the lungs (pneumonia)
- the urinary tract
- the membranes covering the brain (meningitis)
- the abdomen
- the skin and soft tissue
- the genitals with gonococci
- preoperative prophylaxis in colorectal surgery

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CEFOTAXIME INJECTION

Do not use Cefotaxime Injection:
- if you are allergic (hypersensitive) to cefotaxime or any other cephalosporins
- if you previously had acute and/or severe allergic reactions to penicillin or any other beta-lactam antibiotic

If given as an injection into the muscle:
Your doctor may consider it necessary to inject this medicine into a muscle. In this case, the doctor will add lidocaine to the injection to make it less painful. However, this method of administering the injection will not be suitable for everyone and **should not be given:**
- to infants under 30 months
- if you are allergic (hypersensitive) to lidocaine or other local anaesthetics of the amide type
- if you have irregular heartbeat
- if you have heart problems which can cause shortness of breath or ankle swelling
- if you are receiving Cefotaxime Injection intravenously (directly into your bloodstream)

Please inform your doctor if one of these applies to you so that your doctor can decide on the form of application.

Warnings and precautions
Tell your doctor or healthcare professional if:
- you have ever had an allergic or hypersensitive reaction to penicillin or other medicines from the penicillin family (beta-lactam-antibiotics)
- experience skin reactions. Contact your doctor immediately
- you suffer from severe allergies or asthma
- you develop **severe persistent (bloody) diarrhoea**. You may have an inflammation of the large intestine caused by the use of cefotaxime. In that case, the use of Cefotaxime Injection **must be stopped immediately.** Do not take medicines that reduce bowel movements
- you have **kidney problems**
- you are on a low-sodium (low salt) diet

If any of these apply to you, your doctor may want to change your treatment or give you special advice.

Cefotaxime Injection may cause you to become infected with organisms that are unsusceptible to antibiotics, so your doctor will monitor your condition. If you become infected, your doctor may start a specific therapy.

This medicine can alter the results of some blood and urine tests. If you are having blood tests (such as Coombs' test) or urinary sugar tests (the Fehling's type which test for reducing sugars) tell your doctor you are taking this medicine as this medicine may cause false positive results.

Your doctor may decide to do tests on your blood if you are given Cefotaxime Injection for longer than 7 days.

Other medicines and Cefotaxime Injection
Please tell your doctor or healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Concomitant intake of:
- other antibiotics (such as penicillins, aminoglycosides, tetracyclines, erythromycin and chloramphenicol)
- diuretics (e.g. furosemide)
- probenecid (for the treatment of gout and arthritis) may increase or decrease the effect of Cefotaxime Injection. Inform your doctor if you are in treatment with these medicines

The efficacy of oral contraceptives may be decreased by concomitant use of cefotaxime. Therefore during treatment with Cefotaxime Injection additional contraceptive methods should be used.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or are planning to become pregnant, your doctor has to determine if a treatment with Cefotaxime Injection is suitable for you.

Cefotaxime Injection excretes in breast milk in low concentrations. Therefore it should not be used during breast-feeding.

Driving and using machines
The effect of cefotaxime on the ability to drive and use machines has not been investigated. However, this medicine may cause impairment of consciousness, abnormal movements and dizziness in some patients. If this happens, do not drive or use machines.

Important information about some of the ingredients of Cefotaxime Injection
This medicinal product contains 48 mg sodium per gram. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE CEFOTAXIME INJECTION

Cefotaxime Injection is normally given by a doctor or nurse. You should check with your doctor or healthcare professional if you are not sure.

Cefotaxime Injection should always be administered intravenously (in a vein) or intra muscular (in a muscle). The injection will always be administered by a doctor.

Dose, method of application and intervals between injections depend on the sensitivity of the micro-organism, the severity of your infection and your condition.

How much Cefotaxime Injection will be given?

Adults and adolescents (12 to 16-18 years) will usually be given 1 g every 12 hours. In severe infections, this may be increased up to 12 g per day, given in 3-4 doses. For infections caused by sensitive Pseudomonas species, daily doses of greater than 6 g will usually be required.

Children: The dose will depend on the size of your body; the usual dose is 50-100 mg/kg/day in 2-4 divided doses. In very severe infections, doses of up to 200 mg/kg/day may be required.

Babies (0-27 days): The recommended dosage is 50 mg/kg/day in 2-4 divided doses. In severe infections, doses of up to 150-200 mg/kg/day may be required.

Use in patients with kidney problems
If the condition of the kidneys is very poor (creatinine clearance of ≤ 5 ml/min), your doctor will reduce the dosage by half after you have received an initial normal dose.

If you think you have been given too much Cefotaxime Injection
This is not likely, as the injection is given to you by a doctor. If you feel bad after administration of the injection, please contact your doctor immediately.

If your doctor stops giving you Cefotaxime Injection
The doctor will continue treatment with Cefotaxime Injection until the infection treated is relieved.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefotaxime Injection can cause side effects, although not everybody gets them.

Very common side effects (affects more than 1 user in 10):
- transient pain at the injection site

Uncommon side effects (affects 1 to 10 users in 1,000):
- reduced amount of white blood cells or of blood platelets
- reactions called "Jarisch-Herxhemier" which includes fever, shivering, headache and joint pain
- convulsions
- diarrhoea
- changes in liver values
- rash, itching and special skin rash named urticaria
- impaired kidney function
- fever
- inflammation at the injection site and of your veins (thrombophlebitis)

Not known (frequency cannot be estimated from the available data):
- infections with unsusceptible organisms ("Superinfections")
- decrease in the number of a type of white blood cells (neutropenia)
- serious condition in which white blood cells decrease in number or disappear altogether (Agranulocytosis), sometimes also called 'granulocytopenia'
- low levels of red blood cells (anaemia)
- anaphylactoid reactions (that may range from mild to severe, including a sudden, generalised allergic reaction that may lead to a life-threatening "anaphylactic" shock [e.g. difficulty in breathing, drop of blood pressure, fast pulse])
- severe allergic reactions as swelling of the face, throat, and lips (angiooedema)
- bronchial spasms
- headache and dizziness
- brain disorders (e.g. impairment of consciousness, abnormal movements)
- irregular heartbeat
- feeling sick, vomiting
- pain in the abdomen
- a serious bacterial infection of your gut known as pseudomembranous colitis (including severe, persistent or bloody diarrhoea associated with abdominal pain or fever)
- hepatitis, sometimes with jaundice
- serious skin conditions such as Steven-Johnsons syndrome, erythema multiforme and toxic epidermal necrolysis
- reversible inflammation of the kidneys
- reactions to lidocaine if Cefotaxime Injection is given as a injection into a muscle

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CEFOTAXIME INJECTION

Your doctor or pharmacist is responsible for storing Cefotaxime Injection. They are also responsible for disposing of any unused Cefotaxime Injection correctly.

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

Do not use Cefotaxime Injection after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

Store the unopened vial below 25°C. Keep container in the outer carton.
Once the powder has been dissolved, the solution should be used immediately or stored at 2-8°C and discarded after 24 hours.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cefotaxime Injection contains
The active substance in Cefotaxime Injection is cefotaxime as the sodium salt. The total sodium (salt) content is approximately 24 or 48 mg respectively.

1 vial Cefotaxime Injection, 0.5 g contains 0.524 g cefotaxime sodium, corresponding to 500 mg cefotaxime.

1 vial Cefotaxime Injection, 1 g contains 1.048 g cefotaxime sodium, corresponding to 1 g cefotaxime.

There are no other ingredients.

What Cefotaxime Injection looks like and contents of the pack
Cefotaxime Injection is a white to slightly yellow powder in a colourless glass vial. It is supplied in 500 mg or 1 g vials with 1, 5, 10, 25 or 50 vials in a carton.
Not all pack sizes may be marketed

PL 42671/0004 - Cefotaxime 500 mg powder for solution for injection
PL 42671/0005 - Cefotaxime 1 g powder for solution for injection or infusion

Marketing Authorisation Holder:
Cox Pharmaceutical Ltd
Elscot House, Arcadia Avenue,
London N3 2JU, UK

Manufacturer:
IPG Pharma Ltd
Atrium Court
The Ring
Bracknell
RG12 1BW, UK

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INFORMATION FOR THE DOCTOR
Cefotaxime 500 mg Injection and 1 g Injection or Infusion
INFORMATION FOR THE HEALTH CARE PROFESSIONAL

Reconstitution:
From the calculated dose, determine the appropriate number of vials to be used. Add the recommended volume of reconstitution solution and shake well until the contents of the vial have dissolved completely.

Route of administration	Reconstitution solution	Diluent required		Displacement volume	
		500 mg	1 g	500 mg	1 g
Intravenous or intramuscular injection	Water for Injections Ph. Eur.	2 ml	4 ml	0.45 ml	0.9 ml
Intravenous infusion	Water for Injections Ph. Eur. Sodium Chloride Injection BP 5% Dextrose Injection BP Dextrose and Sodium Chloride Injection BP Sodium lactate Injection BP	40-100 ml for 1-2 g of Cefotaxime			

Prepared injections should be used immediately.
Prepared infusion to be administered over 20-60 minutes.
Cefotaxime is for single patient use only, discard any unused solution.
Cefotaxime and aminoglycosides should not be mixed in the same syringe or perfusion fluid.

Reconstitute with:
Water for Injections Ph. Eur.
Sodium Chloride Injection BP
5% Dextrose Injection BP
Dextrose and Sodium Chloride Injection BP
Sodium lactate Injection BP
Metronidazole Infusion (500 mg/100 ml)
1% lidocaine/lignocaine (freshly prepared)
The compatibility of cefotaxime in other infusion fluids should be checked before use.
The reconstituted solution should be clear, do not use the solution if particles are present.

Artwork Panel

Product: Cefotaxime 500mg, 1g
Client: Cox Pharmaceutical Ltd
Date: 17-12-20
Artwork Code: A326/UK/C
Version No:
Artwork Ref: COX_Cefotaxime_500mg, 1g_PIL_A326-UK
Pack Type: PIL (Leaflet)
Dimensions: 210*400mm

PL No: 42671/0004/0005
Barcode: n/a

Fonts: Arial
Min Font Point: Min point 9pt

Technical NON-Printed items:
Braille: n/a
Cutter:

Colour References:
PMS 1:
PMS 2:
PMS 3:
Black:

Approval / Sign off by appointed representative

Verified by:
Regulatory approved by:
Commercial approved by:
QA Approved by:

HA Approval Received by: