Cefotaxime 0.5 g powder for solution for injection
Cefotaxime 1 g powder for solution for injection
Cefotaxime 2 g powder for solution for injection

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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

SANDOZ

1 What Cefotaxime is and what it is used for

The active ingredient in this medicine is cefotaxime. Cefotaxime is an antibiotic. Cefotaxime belongs to a group of antibiotics called 'cephalosporins'.

It is suitable for the treatment of bacterial infections such as:

- lung infections (lower respiratory tract),
- bladder and kidney infections (urinary tract),
- skin infections and infections of the layers (soft tissue) beneath the skin,
- genital tract infections (including gonorrhoea which is a sexually transmitted disease),
- abdominal infections (peritonitis),
- brain infections (meningitis).

2 What you need to know before you use Cefotaxime

DO NOT USE CEFOTAXIME
- if you are allergic (hypersensitive) to cefotaxime, any other cephalosporin type of antibiotic or any of other ingredients of this medicine.
- if you have ever had an severe allergic reaction to penicillin or other medicines from the penicillin family (beta-lactam-antibiotics).

If you are not sure, ask your doctor or healthcare professional.

Warnings and precautions
Talk to your doctor before using Cefotaxime if
- 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 **must be stopped immediately**. Do not take medicines that reduce bowel movements.
- your treatment lasts for longer than 7 days. In this case your doctor will order blood sample controls. If your white blood cell count decreases your doctor will eventually stop the treatment
- 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.

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. The product information of the chosen lidocain-containing medicinal product must be regarded.

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 for longer than 7 days.

Other medicines and Cefotaxime
Tell your doctor if you are taking or have recently taken or might take any other medicines, including medicines you have obtained without a prescription. This is important because some medicines should not be taken with Cefotaxime

Do not take Cefotaxime together with these medicines:
- Certain **antibiotics** – **tetracyclines** (such as doxycycline or minocycline), **erythromycin**, **chloramphenicol**. They may not work properly if used with Cefotaxime.

The use of the following medicines is not recommended:
- Any **other antibiotics**. They may not work properly if used with Cefotaxime.
- **Probenecid** (for gout). This can increase the time it takes for cefotaxime to leave your body.
- Medicines that may affect the way your kidneys work, like **aminoglycoside antibiotics** or diuretics (water tablets such as **furosemide**).

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Cefotaxime can pass to a baby in the womb or through breast milk. If you are pregnant or breast-feeding, your doctor will decide whether Cefotaxime is right for you.

Driving and using machines
There are no reports that this medicine may affect your ability to drive or use machines. However, certain side effects could occur (see section 4), which may influence your ability to drive or use machines. If you feel dizzy, do not drive or use any machines.

Cefotaxime contains sodium
Cefotaxime 0.5 g contains 24 mg sodium (main component of cooking/table salt) in each unit. This is equivalent to 1.2 % of the recommended maximum daily dietary intake of sodium for an adult.

Cefotaxime 1 g contains 48 mg sodium (main component of cooking/table salt) in each unit. This is equivalent to 2.4 % of the recommended maximum daily dietary intake of sodium for an adult.

Cefotaxime 2 g contains 96 mg sodium (main component of cooking/table salt) in each unit. This is equivalent to 4.8 % of the recommended maximum daily dietary intake of sodium for an adult.

3 How to use Cefotaxime

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Cefotaxime is normally given by a doctor or nurse.
It is given:
- by slow injection (for 3-5 minutes) or through a drip (for 20-60 minutes) into one of your veins (intravenous) or
- by deep injection into a large muscle of the buttock (intramuscular).

The dose of Cefotaxime is determined by your doctor depending on your age, your weight and the severity of the infection and on how well your liver and kidneys are working. Your doctor will explain this to you.

The recommended dose is
Adults and children over 12 years who weigh more than 50 kg:
- 2-6 g daily. The daily dose should be divided.
- In severe infections the dose may go up to 12 g daily.

Infants and children (1 month to 12 years of age) who weigh less than 50 kg:
- 50–150 mg for each kg of body weight per day in two to four divided doses.
- In severe infections the dose may go up to 200 mg for each kg of body weight per day in divided doses.

Infants (younger than four weeks old):
- 50 mg per kg body weight daily in two to four divided doses.
- In severe infections the dose may go up to 150-200 mg for each kg of body weight per day.

Elderly:
The usual dosage for adults does not need to be adjusted if the kidney function and liver function are good.

Special dosage information:
- Gonorrhoea: a single injection of 0.5 - 1 g is required.
- Uncomplicated bladder or kidney infections: the dose is 1 g twice daily
- Brain infections: in adults the dose is 6-12 g daily, in children 150-200 mg for each kg of body weight per day and in newborns 50 mg for each kg of body weight per day.
- Abdominal infections: Cefotaxime may be used in combination with other antibiotics.

In special cases Cefotaxime may be injected directly into a large muscle. In this case Cefotaxime powder for solution for injection may be dissolved in a medicine called lidocaine which is intended to make the injection less painful.

Continued on the next page >>

The following information is intended for medical or healthcare professionals only:

Cefotaxime 0.5 g powder for solution for injection
Cefotaxime 1 g powder for solution for injection
Cefotaxime 2 g powder for solution for injection

cefotaxime

This is an extract from the Summary of Product Characteristics to assist in the administration of Cefotaxime. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the SPC.

For slow intravenous injection / infusion and intramuscular injection.

INCOMPATIBILITIES WITH DILUENTS AND OTHER MEDICINAL PRODUCTS
- Cefotaxime should not be added with other antibiotics, in the same syringe or solution for infusion. This concerns especially aminoglycosides.
- Cefotaxime should not be mixed with solutions containing sodium bicarbonate.

INSTRUCTIONS FOR USE, HANDLING AND DISPOSAL
Aseptic techniques should be used to reconstitute the solution. The reconstituted solution should be administered immediately.

Cefotaxime is compatible with several commonly used intravenous infusion fluids:
- Water for Injection
- 0.9 % Sodium Chloride solution
- 5 % Glucose solution
- 5 % Glucose/0.9 % Sodium Chloride solution
- Ringer-lactate solution
- 5 % Metronidazole solution
- Dextran 40 in 0.9 % Sodium Chloride solution
- Dextran 40 in 5 % Glucose solution

The compatibility of cefotaxime in other infusion fluids should be checked before use. Following reconstitution the solution should be clear and pale yellowish to brown-yellowish. Do not use if any particulate matter is visible. Withdraw only one dose. Any unused solution should be discarded.

Method of administration:
In order to prevent any risk of infection, the preparation of the infusion should be done in close aseptic conditions. Do not delay the infusion after the preparation of the solution. Cefotaxime and aminoglycosides should not be mixed in the same syringe or perfusion fluid.

- **Intravenous infusion**

For *short intravenous infusion* Cefotaxime 1 g / 2 g should be dissolved in 40-50 ml Water for Injections or in another compatible fluid (e.g. glucose 10%). After preparation the solution should be given as a 20 minute intravenous infusion.

For *long lasting intravenous infusion*
Cefotaxime 2 g should be dissolved in 100 ml of a suitable fluid e.g. 0.9% sodium chloride or isotonic glucose solution or other compatible fluids for infusions.
After preparation the solution should be given as a 50-60 minute intravenous infusion.

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If you use more Cefotaxime than you should
As you will be given Cefotaxime by a doctor or nurse, you are unlikely to be given the wrong dose. However, if you experience bad side effects or think you have been given too much, tell your doctor immediately.

If you forget to use Cefotaxime
If you think you have not been given a dose of Cefotaxime, tell your doctor immediately.

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

4 Possible side effects

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

You must contact your doctor immediately if you notice any of the following:

Uncommon: may affect up to 1 in 100 people
- Increased tendency to bleed or bruise more easily caused by a fall in the number of blood platelets (thrombocytopenia), fever, sore throat or mouth ulcers due to infections caused by a low level of white blood cells (leucopenia) or high level of a specific type of white blood cells (eosinophilia)

Not known: frequency cannot be estimated from the available data
- Inflammation of the bowels, called colitis (or antibiotic-associated colitis), causing severe long-lasting watery or bloody diarrhoea with stomach cramps and fever
- Serious blood problems, including changes in the numbers of some white blood cells (which may cause frequent infections, fever, severe chills, sore throat, or mouth ulcers)
- Damage to red blood cells (causing tiredness, being short of breath or looking pale)
- Severe allergic reactions with symptoms such as swelling of the lips, tongue, face and neck, sudden difficulty in breathing, speaking and swallowing;
- Headache, dizziness, convulsions (fits) (these may be symptoms of a brain disorder called encephalopathy)
- Changes in heart beat (rhythm or rate), after a very quick injection into a vein
- Yellow skin and eyes, loss of appetite, light-coloured urine caused by inflammation of the liver.
- Skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge).
- A widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Increased or reduced urine output, or traces of blood in your urine, sometimes with swollen limbs and / or flank pain caused by kidney problems
- For intramuscular injection: combination with lidocaine can cause systemic reactions

Other possible side effects:

Very common: may affect more than 1 in 10 people
- Intramuscular injection may be painful

Uncommon: may affect up to 1 in 100 people
- People being treated for infections with bacteria called spirochetes often show symptoms like fever and shivering which are described as 'Herxheimer reaction' and indicate the effectiveness of the therapy.
- Changes in the results of blood tests that check how the liver and kidneys are working
- Fever
- Allergic reactions such as skin rash (nettle rash), itchy skin
- Painful swelling and inflammation where the injection is given into a vein
- Soft stools or diarrhoea
- Convulsions

Not known: frequency cannot be estimated from the available data
- Feeling sick (nausea) and being sick (vomiting)
- Pain in your stomach (abdomen)

Your doctor may want to perform tests during your treatment to measure any changes.

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 the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in 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

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 carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container in the outer carton in order to protect from light.

For storage conditions of the reconstituted/ diluted medicinal product, see the area of the package leaflet headed 'The following information is intended for medical or healthcare professionals only'.

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 contains
The active substance is cefotaxime (as sodium salt).

Each vial of 15 ml contains 500 mg of cefotaxime.
Each vial of 20 ml contains [1 g / 2 g] of cefotaxime.
Each infusion bottle of 50 ml contains 2 g of cefotaxime.

The medicinal product contains no other ingredients than the active substances.

What Cefotaxime looks like and contents of the pack
This medicinal product is a powder for solution for injection.
The powder is white to slightly yellow, contained in a colourless type 3 glass vial with rubber closures and covered with aluminium caps. The vials are packed in carton boxes.
Pack sizes:

1 x 15 ml vial with powder for solution for injection
10 x 15 ml vial with powder for solution for injection
25 x 15 ml vial with powder for solution for injection
50 x 15 ml vial with powder for solution for injection
100 x 15 ml vial with powder for solution for injection

Multipack: 5 cartons with 1 vial with powder for solution for injection
Multipack: 10 cartons with 1 vial with powder for solution for injection

Cefotaxime 1g Powder for Solution for Injection
This medicinal product is a powder for solution for injection or infusion.
The powder is white to slightly yellow, contained in a colourless type 3 glass vial with rubber closures and covered with aluminium caps. The vials are packed in carton boxes.

1 x 20 ml vial with powder for solution for injection/infusion
10 x 20 ml vial with powder for solution for injection/infusion
25 x 20 ml vial with powder for solution for injection/infusion
50 x 20 ml vial with powder for solution for injection/infusion
100 x 20 ml vial with powder for solution for injection/infusion

Multipack: 5 cartons with 1 vial with powder for solution for injection/infusion
Multipack: 10 cartons with 1 vial with powder for solution for injection/infusion

Cefotaxime 2g Powder for Solution for Injection
This medicinal product is a powder for solution for injection or infusion.
The powder is white to slightly yellow, contained in a colourless type 3 glass vial or in a colourless type 2 infusion bottle with rubber closures and covered with aluminium caps. The vials are packed in carton boxes.

1 x 20 ml vial with powder for solution for injection/infusion
10 x 20 ml vial with powder for solution for injection/infusion
25 x 20 ml vial with powder for solution for injection/infusion
50 x 20 ml vial with powder for solution for injection/infusion
100 x 20 ml vial with powder for solution for injection/infusion

Multipack: 5 cartons with 1 vial with powder for solution for injection/infusion
Multipack: 10 cartons with 1 vial with powder for solution for injection/infusion

1 x 50 ml infusion bottle with powder for solution for injection/infusion
10 x 50 ml infusion bottle with powder for solution for injection/infusion
25 x 50 ml infusion bottle with powder for solution for injection/infusion
50 x 50 ml infusion bottle with powder for solution for injection/infusion
100 x 50 ml infusion bottle with powder for solution for injection/infusion

Multipack: 5 cartons with 1 infusion bottle with powder for solution for injection/infusion
Multipack: 10 cartons with 1 infusion bottle with powder for solution for injection/infusion

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Sandoz Ltd.
Frimley Business Park
Frimley, Camberley
Surrey, GU16 7SR.
UK.

This leaflet was last revised in 12/2018.

- **Intravenous injection**

Cefotaxime 0.5 g / 1 g / 2 g should be dissolved in 2 ml / 4 ml / 10 ml Water for Injections and should be injected over a period of 3-5 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.

- **Intramuscular injection**

Cefotaxime 0.5 g / 1 g should be dissolved in 2 ml / 4 ml Water for Injections. The solution should be administered by deep intramuscular injection. In order to prevent pain from injection Cefotaxime 0.5 g / 1 g may be dissolved in 2 ml / 4 ml 1 % Lidocaine Hydrochloride (only for adults). Solutions with lidocaine must not be administered intravenously. If the total daily dose is more than 2 g, the intravenous administration should be chosen. In the case of severe infections, intramuscular injection is not recommended. The product information of the chosen lidocain-containing medicinal product must be regarded.

The following table shows the volume of dilution for each vial size

	Method of administration			
Vial size	Short intravenous infusion	Long lasting intravenous infusion	Intravenous injection	Intramuscular injection
0.5 g	-	-	2 ml	2 ml
1 g	40-50 ml	-	4 ml	4 ml
2 g	40-50 ml	100 ml	10 ml	-