

DBL™ Cefotaxime Sodium

cefotaxime sodium (kef-oh-TACK-sim SO-dee-uhm)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Cefotaxime Sodium. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DBL Cefotaxime Sodium against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What DBL Cefotaxime Sodium is used for

DBL Cefotaxime Sodium is an antibiotic used to treat infections of the:

- kidneys and bladder
- blood (septicaemia)
- skin and flesh immediately under the skin
- bones
- heart valves
- brain (meningitis)
- abdomen (peritonitis)
- some sexually transmitted infections (gonorrhoea).

It is also used to prevent infections before, during and after surgery.

Cefotaxime will not work against infections caused by viruses such as colds or the flu.

Cefotaxime belongs to a group of antibiotics called cephalosporins (kef-a-loe-SPOR-ins). These antibiotics work by killing the bacteria that are causing your infection.

Your doctor may have prescribed cefotaxime for another reason.

Ask your doctor if you have any questions about why cefotaxime has been prescribed for you.

This medicine is available only with a doctor's prescription.

DBL Cefotaxime Sodium is not addictive.

Before you are given DBL Cefotaxime Sodium

When you must not be given it

DBL Cefotaxime Sodium should not be given to you if you have an allergy to:

- cefotaxime
- any similar medicines known as cephalosporins

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Cefotaxime should not be given to you if you have had a major allergic reaction to penicillins.

Cefotaxime should not be mixed with lignocaine and given:

- if you have had an allergic reaction to lignocaine or other local anaesthetics
- if you have heart failure or heart block
- to infants less than 30 months old.

Sometimes DBL Cefotaxime Sodium is mixed with lignocaine hydrochloride so that the injection into the muscle is less painful.

If you are not sure whether you should be given this medicine, talk to your doctor.

Do not use DBL Cefotaxime Sodium if the packaging is torn or shows signs of tampering.

Before you are given it

Tell your doctor if you have had any type of allergic reaction to penicillin medicines.

You may have an increased chance of being allergic to cefotaxime if you are allergic to penicillins.

Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have ever had, any of the following health problems or medical conditions:

- kidney disease
- liver disease
- stomach or bowel problems
- asthma.

Tell your doctor if you are:

- a low white blood cell count (neutropenia)
- you are on a low salt diet.

Tell your doctor if you are pregnant or intend to become pregnant.

DBL Cefotaxime Sodium is not recommended for use during pregnancy. If there is a need to consider cefotaxime during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor if you are breast-feeding or plan to breast-feed.

DBL Cefotaxime Sodium is not recommended while you are breast-feeding. If there is a need to consider cefotaxime while you are breast feeding, your doctor will discuss the possible risks and benefits of using it.

If you have not told your doctor about any of the above, tell them before you are given cefotaxime.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with cefotaxime. These include:

- aminoglycoside antibiotics (such as gentamicin)

- other antibiotic medicines (such as tetracyclines, erythromycin and chloramphenicol)
- probenecid, a medicine used to treat gout
- "water" tablets or diuretics (such as frusemide).
- opiates and diphenoxylate (medicines used to stop diarrhoea).

These medicines may be affected by cefotaxime, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Talk to your doctor about the need for an additional method of contraception while being given DBL Cefotaxime Sodium.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with cefotaxime.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while being given DBL Cefotaxime Sodium.

How DBL Cefotaxime Sodium is given

DBL Cefotaxime Sodium may be given by:

- direct injection into a vein or as a slow injection or infusion (intravenous drip) into a vein

- as a deep injection into a large muscle.

DBL Cefotaxime Sodium should only be given by a doctor or nurse.

Your doctor will decide what dose you will receive and how long you will receive DBL Cefotaxime Sodium for. This depends on your infection and other factors, such as your weight. For most infections, it is usually given in divided doses throughout the day.

Sometimes only a single dose of DBL Cefotaxime Sodium is required for the treatment of certain infections.

If you are given too much (overdose)

As DBL Cefotaxime Sodium is given under medical supervision; it is very unlikely that you will receive too much.

Immediately telephone your doctor the Poisons Information Centre 13 11 26 for advice if you think that you or anyone else has taken/used too much DBL Cefotaxime Sodium. You may need urgent medical attention.

Symptoms of a cefotaxime overdose may include:

- stomach upsets
- headache
- dizziness

- seizures.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL Cefotaxime Sodium

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it occurs several weeks after cefotaxime has been stopped. Do not take any diarrhoea medicine without first checking with your doctor.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

If you get a sore white mouth or tongue while being given or soon after stopping cefotaxime, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of DBL Cefotaxime Sodium allows fungi to grow and the above symptoms to occur. Cefotaxime does not work against fungi.

If you become pregnant while you are being treated with cefotaxime, tell your doctor immediately.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are being given cefotaxime.

If you have to test your urine for sugar while you are being given DBL Cefotaxime Sodium, make sure your doctor knows which type of test you use.

This medicine may affect the results of some of these tests.

If you have to have any blood tests, tell your doctor you are being given DBL Cefotaxime Sodium.

This medicine may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacist who are treating you that you are being given DBL Cefotaxime Sodium.

Things you must not do

Do not give DBL Cefotaxime Sodium to anyone else, even if they have the same condition as you.

Do not use DBL Cefotaxime Sodium to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how DBL Cefotaxime Sodium affects you.

This medicine may cause dizziness, drowsiness, seizures or unusual body movements in some people. If you have any of

these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with DBL Cefotaxime Sodium.

Cefotaxime helps most people with infections, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side-effects.

Ask your doctor or pharmacist to answer any questions you may have.

While using it

Tell your doctor or nurse if you notice any of the following and they worry you:

- a white, furry, sore tongue and mouth (oral thrush)
- a sore and itchy vagina and/or discharge (vaginal thrush)
- signs of frequent infections such as fever, sore throat, swollen glands or mouth ulcers
- nausea or diarrhoea
- pain, swelling, redness or tenderness near the injection site

- skin rash
- itchiness

These side effects are usually mild.

Tell your doctor or nurse immediately if you notice any of the following:

- severe blisters and bleeding in the lips, eyes, mouth, nose or genitals
- itchy spots accompanied by fever and feeling unwell
- ulceration or lesions on the skin or in the mouth
- severe abdominal or stomach cramps
- loss of appetite
- severe persistent diarrhoea which may also be bloody. It may develop during treatment or up to several weeks after you stop cefotaxime
- signs of an allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing
- fast or irregular heartbeat
- changes in the rhythm or rate of the heartbeat
- chest pain

- blood in the urine or decreased urine output or fluid retention with swelling of the legs, ankles or feet
- unusual bleeding or bruising under the skin
- signs of anaemia, such as tiredness, headache, dizziness being short of breath when exercising or looking pale
- yellowing of the skin or eyes, also known as jaundice
- seizures or abnormal movements.

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

After being given DBL Cefotaxime Sodium

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with DBL Cefotaxime Sodium:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, these side effects are rare.

Do not take any diarrhoea medicine without first checking with your doctor.

This medicine can change bacteria, which is normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given DBL Cefotaxime Sodium

Storage

DBL Cefotaxime Sodium will be stored in the hospital pharmacy or on the ward.

DBL Cefotaxime Sodium should be kept in a cool, dry place, protected from heat and light, where the temperature stays below 25°C.

The reconstituted solution must be used immediately and any unused solution should be discarded.

Product description

What it looks like

DBL Cefotaxime Sodium is a white to pale yellow crystalline powder. It is supplied in a glass vial with a rubber stopper in packs of 1 vial.

Ingredients

DBL Cefotaxime Sodium contains the active ingredient Cefotaxime Sodium, equivalent to 1 g of Cefotaxime.

Each gram of Cefotaxime contains 48.2 mg of sodium.

DBL Cefotaxime Sodium does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Pfizer Australia Pty Ltd

Sydney, NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au .

Australian Register Numbers

DBL Cefotaxime Sodium 1 g, AUST R 78702.

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