

DBL™ Cefotaxime Sodium

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given DBL Cefotaxime Sodium?

DBL Cefotaxime Sodium contains the active ingredient Cefotaxime Sodium.

DBL Cefotaxime Sodium is an antibiotic used to treat infections of the kidneys and bladder, blood, skin and flesh immediately under the skin, bones, heart valves, brain, abdomen and some sexually transmitted infections (gonorrhoea).

For more information, see Section [1. Why am I being given DBL Cefotaxime Sodium ?](#) in the full CMI.

2. What should I know before I am given DBL Cefotaxime Sodium?

Do not use if you have ever had an allergic reaction to DBL Cefotaxime Sodium or any similar medicines known as cephalosporins or if you have had a major allergic reaction to penicillin. 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 or to infants less than 30 months old.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given DBL Cefotaxime Sodium?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Cefotaxime Sodium and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given DBL Cefotaxime Sodium?

DBL Cefotaxime Sodium should only be given by a doctor or nurse. It may be given by direct injection into a vein or as a slow injection or infusion (intravenous drip) into a vein or as a deep injection into a large muscle. 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. More instructions can be found in Section [4. How will I be given DBL Cefotaxime Sodium?](#) in the full CMI.

5. What should I know while being given DBL Cefotaxime Sodium ?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are being given DBL Cefotaxime Sodium.If your 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.
Things you should not do	<ul style="list-style-type: none">Do not use if you have ever had an allergic reaction to DBL Cefotaxime Sodium or any similar medicines known as cephalosporins or if you had a major allergic reaction to penicillin or to lignocaine. DBL Cefotaxime Sodium should not be given if you are pregnant or breastfeeding.
Driving or using machines	<ul style="list-style-type: none">DBL Cefotaxime Sodium may affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">DBL Cefotaxime Sodium will be stored in the hospital pharmacy or on the ward in a cool, dry place, protected from heat and light, where the temperature stays below 25°C.

For more information, see Section [5. What should I know while being given DBL Cefotaxime Sodium?](#) in the full CMI.

6. Are there any side effects?

Side effects include white, furry, sore tongue and mouth, a sore and itchy vagina and/or discharge, 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 and itchiness. Some serious side effects include signs of an allergic reaction, such as rash, itching or hives, swelling of the face and lips, shortness of breath, wheezing or difficulty breathing, severe blisters and bleeding, ulcerations or lesions of the skin or in the mouth, severe stomach cramps, watery and severe diarrhoea, fever in combination with cramps/diarrhoea. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Cefotaxime Sodium

Active ingredient(s): *Cefotaxime sodium*.

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Cefotaxime Sodium. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Cefotaxime Sodium.**

Where to find information in this leaflet:

- [1. Why am I being given DBL Cefotaxime Sodium?](#)
- [2. What should I know before I am given DBL Cefotaxime Sodium?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given DBL Cefotaxime Sodium?](#)
- [5. What should I know while being given DBL Cefotaxime Sodium?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given DBL Cefotaxime Sodium?

DBL Cefotaxime Sodium contains the active ingredient **Cefotaxime Sodium**. DBL Cefotaxime Sodium is an antibiotic. Cefotaxime belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection. DBL Cefotaxime Sodium is 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.

Your doctor may have prescribed cefotaxime for another reason.

2. What should I know before I am given DBL Cefotaxime Sodium?

Warnings

Do not use DBL Cefotaxime Sodium if:

- you are allergic to cefotaxime or any similar medicines known as cephalosporins
- you have had a major allergic reaction to penicillins
- if you are pregnant or breastfeeding

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.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any of the following medical conditions: kidney disease, liver disease, stomach or bowel problems or asthma.
- Have a low white blood cell count (neutropenia)
- are on a low salt diet
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

DBL Cefotaxime Sodium should not be given if you are pregnant or breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Cefotaxime Sodium and affect how it works. 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 furosemide).

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Cefotaxime Sodium.

4. How will I be given DBL Cefotaxime Sodium?

How much will be 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 of DBL Cefotaxime Sodium you will receive and for how long you will receive it. 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 DBL Cefotaxime Sodium

As DBL Cefotaxime Sodium is given under medical supervision; it is very unlikely that you will receive too much. If you think that you have been given too much, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given DBL Cefotaxime Sodium?

Things you should do

Call your doctor straight away if:

- the symptoms of your infection do not improve within a few days, or if they become worse
- you get severe diarrhoea. 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.
- you get a sore white mouth or tongue while being given or soon after stopping cefotaxime. 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.

- you become pregnant while you are being treated with 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Cefotaxime Sodium affects you.

DBL Cefotaxime Sodium 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.

Drinking alcohol

No information available.

Looking after your medicine

- 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.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any medicine that has passed the expiry date.

This medicine should only be used in one patient and any unused medicine should be discarded.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• 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	Speak to your doctor if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> itchiness 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> a white, furry, sore tongue and mouth (oral thrush) a sore and itchy vagina and/or discharge (vaginal thrush) 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 loss of appetite 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 severe abdominal cramps, severe persistent diarrhoea which may be bloody, fever (with or without cramps/diarrhoea). It may develop during treatment or several weeks after you stop cefotaxime 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Cefotaxime Sodium contains

Active ingredient (main ingredient)	Cefotaxime Sodium (equivalent to 1 g of Cefotaxime)
Other ingredients (inactive ingredients)	Sodium (each gram of Cefotaxime contains 48.2 mg of sodium)

Do not take this medicine if you are allergic to any of these ingredients.

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

What DBL Cefotaxime Sodium 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 (AUST R 78702).

Who distributes DBL Cefotaxime Sodium

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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