DBL™ Piperacillin and Tazobactam for Injection

piperacillin (pip-ER-uh-sill-in) and tazobactam (tay-zoh-BACK-tam)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBLTM Piperacillin and Tazobactam for Injection. 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 DBLTM Piperacillin and Tazobactam for Injection against the benefits this medicine is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What DBL™ Piperacillin and Tazobactam for Injection is used for

This medicine contains the active ingredients piperacillin and tazobactam. They belong to a group of antibiotics called penicillins that work by killing bacteria.

Piperacillin is an antibiotic that kills many types of bacteria. Tazobactam helps piperacillin to overcome bacteria, which have become resistant to piperacillin.

 DBL^{TM} Piperacillin and Tazobactam for Injection is active

against bacteria, which cause serious infections such as:

- · Chest infections
- Urine infections
- Stomach infections
- · Skin infections
- Gynaecological infections
- Infections of the blood or blood poisoning.

It is also used to treat many other infections.

In children aged 2 to 12 years, piperacillin and tazobactam is used to treat serious infections in the abdomen.

DBLTM Piperacillin and Tazobactam for Injection is not recommended to treat abdominal infections in children under 2 years.

This medicine will not work against infections caused by viruses such as colds or flu.

Your doctor may have prescribed piperacillin and tazobactam for another reason. Ask your doctor if you have any questions about why Medicine Name has been prescribed for you.

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

DBL™ Piperacillin and Tazobactam for Injection is not addictive.

Before you are given DBL™ Piperacillin and Tazobactam for Injection

When you must not be given it

Do not use DBLTM Piperacillin and Tazobactam for Injection if you have ever had an allergic reaction to:

- piperacillin, tazobactam, or any other penicillin antibiotics
- any antibiotic in the cephalosporin group
- medicines called beta-lactamase inhibitors.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

DBLTM Piperacillin and Tazobactam for Injection should not be given to children under two years of age unless directed by the child's doctor.

Before you are given it

You must tell your doctor if you have any of the following conditions:

- allergy to penicillins or cephalosporins
- allergy to any foods, dyes, preservatives or any other medicines
- · kidney disease
- · liver disease

- any other health problems
- you are on a low salt diet

Tell your doctor if you are pregnant or plan to become pregnant

Your doctor will discuss the risks and benefits of using this medicine if you are pregnant.

Tell your doctor if you are breast-feeding.

DBLTM Piperacillin and Tazobactam for Injection passes into breast milk. Therefore, if you are breast-feeding, you should discuss with your doctor whether to stop breast-feeding or stop using this medicine.

If you are being treated with DBLTM Piperacillin and Tazobactam for Injection for gonorrhoea, your doctor should test you for syphilis as well.

DBLTM Piperacillin and Tazobactam for Injection in high doses may hide early symptoms of syphilis without curing it long-term.

If you are not sure whether you should be taking DBLTM
Piperacillin and Tazobactam for Injection, talk to your doctor.

Taking other medicines

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

Some medicines and DBLTM Piperacillin and Tazobactam for Injection may interfere with each other. These include:

- medicines used to treat gout (such as probenicid)
- aminoglycoside antibiotics eg tobramycin
- · vancomycin antibiotics
- medicines used for thinning blood, (such as warfarin or heparin)
- methotrexate, a medicine used to treat cancer, rheumatoid arthritis and other inflammatory conditions
- vecuronium, a muscle relaxant used in surgery.

These medicines may be affected by DBLTM Piperacillin and

Tazobactam for Injection or may affect how well it works. You may need to be given different amounts of your medicine or you may need to be given different medicines.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking DBL TM Piperacillin and Tazobactam for Injection.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine.

How DBL™ Piperacillin and Tazobactam for Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

If you have kidney disease your doctor will adjust the dose to suit you.

How it is given

DBLTM Piperacillin and Tazobactam for Injection is usually given as a slow infusion (drip) into a vein over 20-30 minutes.

This medicine must only be given by a nurse or doctor.

How long it is given for

Your doctor will decide how long you are to receive DBLTM
Piperacillin and Tazobactam for Injection.

The length of time you will be given the medicine depends on the type and severity of your infection.

It should be given for at least five days, and for 48 hours after all signs of illness and fever have gone.

If you are given too much (overdose)

As DBLTM Piperacillin and Tazobactam for Injection is given under medical supervision, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Please contact the Poisons Information Centre in Australia on 131 126 or in New Zealand on 0800 764 766 for advice on overdose management.

Ask your doctor if you have any concerns.

While you are receiving DBL™ Piperacillin and Tazobactam for Injection

If you are given this medicine for a long period of time, your doctor may wish to do some blood tests.

Sometimes blood disorders can occur if you take DBLTM Piperacillin and Tazobactam for Injection.

If a doctor asks you for a urine sample, tell him/her that you are receiving DBL^{TM} Piperacillin and Tazobactam for Injection.

Antibiotics in the penicillin family, including DBLTM Piperacillin and Tazobactam for Injection, can cause interference in some tests for glucose in urine. Penicillins that are excreted in urine can affect the test result. The doctor will request a test which is not affected by penicillins.

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 develop itching or swelling or skin rash or difficulty breathing while you are being given this medicine, tell your doctor or nurse immediately.

If you develop severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after stopping DBLTM Piperacillin and Tazobactam for Injection.

This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care.

Do not take any medicines to treat this diarrhoea without checking with your doctor.

If you become pregnant while you are being given DBLTM
Piperacillin and Tazobactam for Injection, tell your doctor immediately.

If you are about to start taking a new medicine tell your doctor or pharmacist that you are being given piperacillin.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DBLTM Piperacillin and Tazobactam for Injection.

This medicine is effective in most people, but may have unwanted side effects in some.

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 to answer any questions you may have.

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

- increased sweating
- eczema or rash
- severe skin reactions
- dry mouth
- · weakness and tiredness
- hallucinations

- muscle or joint pain or muscle weakness
- fever
- · hot flushes
- · difficulty sleeping
- swelling of the hands, feet and ankles
- swelling or redness along a vein which is extremely tender when touched
- yellowing of skin and eyes (called jaundice)
- · diarrhoea
- · difficulty urinating

These side effects are usually mild.

Tell your doctor as soon as possible if you experience any of the following:

- redness or pain at the injection site
- rash, itchy or red skin
- · nausea or vomiting
- Severe diarrhoea or constipation
- spasms, seizures or fits
- allergic reactions such as hives
- headache, dizziness or lightheadedness.
- white, furry, sore tongue and mouth (oral thrush)
- sore and itchy vagina and/or discharge (vaginal thrush)

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

If any of the following happen, tell your doctor immediately or go to casualty at your nearest hospital:

- tiredness, being short of breath and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- painful red areas, large blisters and peeling of layers of skin.
- Severe rash on the face, the armpits or groin,

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with DBLTM Piperacillin and Tazobactam for Injection.

- 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, this side effect is rare.

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

After using DBL[™] Piperacillin and Tazobactam for Injection

Storage

DBLTM Piperacillin and Tazobactam for Injection will be stored in the pharmacy or on the ward.

DBLTM Piperacillin and Tazobactam for Injection is

stored in a cool, dry place where it stays below 25°C.

Heat and dampness can destroy some medicines.

2 g/ 0.25 g AUST R 128752 (not marketed)

4 g/ 0.5 g AUST R 128753

This leaflet was updated in July 2016

Product description

What it looks like

DBLTM Piperacillin and Tazobactam for Injection is a white to off white powder which is supplied as powder in glass containers (vials).

The powder is mixed with sterile liquid to give a clear, colourless solution for injection by your doctor.

Ingredients

DBL™ Piperacillin and Tazobactam for Injection vials contain piperacillin sodium and tazobactam sodium as the active ingredients and contains no inactive ingredients.

DBLTM Piperacillin and Tazobactam for Injection contains 54.28 mg of Sodium per gram of piperacillin in the combination product.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd ABN 58 097 064 330 Level 3 500 Collins Street Melbourne VIC 3000 Australia

New Zealand Sponsor

Hospira NZ Limited 58 Richard Pearse Drive Airport Oaks, Mangere 2022 Auckland New Zealand

Australian Registration Numbers: