

# DORIBAX<sup>®</sup>

## 500mg Powder for Intravenous Infusion

*Doripenem monohydrate*

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### Consumer Medicine Information

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#### What is in this leaflet

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This leaflet answers some common questions about DORIBAX. 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 being given DORIBAX against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet while being treated. You may need to read it again.

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#### What DORIBAX is used for

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DORIBAX is an antibiotic. It works by killing the bacteria (germs) that cause infections in various parts of the body.

These infections include:

- pneumonia (a serious type of chest or lung infection) that you catch in a hospital or similar setting, including pneumonia that you catch when on a machine that helps you breathe
- complicated infections of the area around your stomach (abdominal infections)
- complicated urinary tract infections, including kidney infections and cases that have spread to the bloodstream.

Your doctor may have prescribed this medicine for another reason.

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

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

#### Before DORIBAX is given

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##### When DORIBAX must not be given

**You must not be given the medicine if you have an allergy to:**

- doripenem, the active ingredient in the medicine
- other antibiotics such as penicillins, cephalosporins or carbapenems (which are used to treat various infections) as you may also be allergic to DORIBAX.

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

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

##### Before the medicine is given:

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- kidney problems. It is particularly important that your doctor knows if there is anything wrong with your kidneys or if you undergo or have undergone dialysis treatment. Your doctor may need to lower your dose of DORIBAX.
- allergies to any medicines, including antibiotics
- diarrhoea before, during or after your treatment with the medicine. This is because you may have a condition known as colitis (an inflammation of the bowel). Do not take any medicine to treat diarrhoea without first checking with your doctor.
- any other stomach problems.

Convulsions have infrequently been reported during treatment with closely related antibiotics. While antibiotics including DORIBAX kill certain bacteria, other bacteria and fungi may continue to grow more than normal. This is called overgrowth. Your doctor will monitor you for overgrowth and treat you if necessary.

You must tell your doctor if you:

- are pregnant or planning to become pregnant. DORIBAX is not recommended for use during pregnancy. However, if there is a need to consider using it during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.
- are breastfeeding or wish to breastfeed. Small amounts of this medicine may pass into breast milk and it may affect the baby. Your doctor will discuss the possible risks and benefits of using this medicine while breastfeeding.

**If you have not told your doctor about any of the above, tell them before you start treatment with the medicine.**

**The medicine must not be given beyond the expiry date (month and year) printed on the pack.**

**The medicine must not be given to children or adolescents (under 18 years of age)** as there is not enough information to be sure that the medicine can be used safely in children or adolescents.

DORIBAX should not be inhaled as it may cause inflammation of the lung (pneumonitis).

### **Taking other medicines:**

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

In particular, tell your doctor if you are taking any of the following:

- sodium valproate/ valproic acid, a medicine used to treat epilepsy, bipolar disorder, migraines or schizophrenia. If you are being treated with this medicine, it is not recommended that you be treated with DORIBAX at the same time.
- probenecid, a medicine used to treat gout or high levels of uric acid in the blood.

These medicines may be affected by DORIBAX or may affect how well it works. Your doctor can tell you what to do if you are using any of these medicines.

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## **Treatment with DORIBAX**

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Your treatment with DORIBAX will take place in a hospital.

### **How much is given:**

Your doctor will decide what dose you will receive and how long you should be treated. The usual dose is 500mg given every eight hours. Each dose is given over a period of one or four hours. The course usually lasts five to fourteen days.

If you have kidney problems, your doctor may lower the dose of DORIBAX to 250mg given over one or four hours, every eight or twelve hours.

### **How it is given:**

The medicine will always be prepared and given to you as an infusion into a vein by a doctor or nurse (this is sometimes known as a “drip”). Your doctor or nurse can explain how the solution for infusion is prepared.

### **If a dose of DORIBAX is missed**

If you are concerned that you have missed a dose of the medicine, talk to your doctor or nurse. It is important that you receive treatment with it as long as your doctor feels it is necessary.

### **If you have received too much (overdose)**

As the medicine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Your doctor or nurse will be closely observing you during this time. Talk to your doctor or nurse immediately if you are concerned that you may have been given too much of this medicine.

**If at some later time you feel really unwell and you think this medicine may be responsible, immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.**

### **Poisons Information Centre telephone numbers:**

- **Australia: 13 11 26**
- **New Zealand: 0800 POISON or 0800 764 766.**

**Keep these telephone numbers handy.**

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

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## While you are given DORIBAX

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### Things you must do

- Always follow your doctor's instructions carefully
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are receiving DORIBAX.

### Things you must not do

- Do not recommend this medicine to anyone else, even if their symptoms seem similar to yours.

### Things to be careful of

#### Driving and using machines

- DORIBAX is not likely to affect your ability to drive or operate machinery.

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## Side Effects

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

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

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

- nausea
- headache
- thrush or fungal infection of the mouth characterised by sore, cream-yellow, raised patches in the mouth
- infection of the female genitals with vaginal discharge

### Tell your doctor as soon as possible if you have any of the following as you may need medical attention:

- diarrhoea
- increase in some liver test enzymes

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

- diarrhoea, usually with blood and mucus, stomach pain, fever

- a condition in which there is a lack of white blood cells characterised by frequent infections such as fever, severe chills, sore throat or mouth ulcers (neutropenia)
- a condition in which there is low blood platelet count leading to bleeding or bruising more easily than normal (thrombocytopenia)
- signs of allergy such as rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body
- severe skin reaction that starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- swelling and redness along a vein which is extremely tender when touched.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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## Product Description

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### Storage

DORIBAX is stored at a temperature below 25°C.

Keep out of the reach and sight of children.

### What it looks like:

DORIBAX is a white to slightly yellowish off-white powder in a glass vial.

Each pack contains 10 single-use vials.

Before injection, the powder is dissolved in a small quantity of Sterile Water for Injection or Normal Saline and is shaken to form a suspension. The suspension is then added to an infusion bag containing Normal Saline or 5% Dextrose and is mixed to complete dissolution.

### Ingredients

The active ingredient is doripenem. Each vial contains doripenem monohydrate equivalent to 500mg doripenem.

There are no inactive ingredients.

**Sponsor**

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This leaflet was prepared in July 2010.

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Pharmaceutical Inc. for doripenem injections.