### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about DBL  $^{\text{TM}}$  Meropenem 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 DBL<sup>TM</sup> Meropenem for Injection 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.

You may need to read it again.

### What DBL™ Meropenem for Injection is used for

DBL<sup>TM</sup> Meropenem for Injection is an antibiotic used in adults and children to treat certain serious infections caused by bacteria, such as:

- · infections of the lungs
- infections of the kidney or bladder (urinary tract infection)
- · febrile neutropenia
- · infections around the stomach or bowel
- infections of the vagina and womb
- · serious skin infections
- infections in the lining of the brain (meningitis)
- infections in the blood stream (septicaemia).

DBL<sup>TM</sup> Meropenem for Injection belongs to a group of medicines called carbapenem antibiotics. These medicines work by killing the bacteria that are causing your infection.

DBL<sup>TM</sup> Meropenem for Injection will not work against fungal or viral infections (such as colds or flu).

DBL<sup>TM</sup> Meropenem for Injection is given by injection and is usually only used in hospitals. It is available only with a doctor's prescription.

# Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

 $\mathsf{DBL^{TM}}$  Meropenem for Injection is not addictive.

# DBL<sup>TM</sup> Meropenem for Injection is not recommended for use in children under the age of 3 months.

Safety and effectiveness in children younger than 3 months have not been established.

### Before you are given DBL™ Meropenem for Injection

### When you must not be given it Do not take DBL<sup>TM</sup> Meropenem for Injection if you have an allergy to:

- any medicine containing meropenem
- any other carbopenems, penicillins or other beta lactam antibiotics
- any of the ingredients listed at the end of this leaflet.

Some of the 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

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

Tell your doctor if you have or have had any of the following medical conditions:

- gastrointestinal or stomach problems, particularly colitis
- · liver problems
- · kidney problems, including dialysis.

Tell your doctor if you have an allergy to any other antibiotics such as other carbapenems, penicillins, cephalosporins or monobactams.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given  $DBL^{\mathrm{TM}}$  Meropenem for Injection.

Taking other medicines

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

Some medicines and DBL<sup>TM</sup> Meropenem for Injection may interfere with each other. These include:

- probenecid a medicine used to treat
  gout
- use of sodium valproate/ valproic acid/ valpromide is not recommended with DBL<sup>TM</sup> Meropenem for Injection
- Oral anticoagulants e.g. warfarin. Your blood results may be affected.

These medicines may be affected by DBL<sup>TM</sup> Meropenem for Injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

## How DBL™ Meropenem for Injection is given.

DBL<sup>TM</sup> Meropenem for Injection is injected into your vein. It must always be given by a doctor or nurse.

Many people who get DBL<sup>TM</sup> Meropenem for Injection in hospital will have a drip (intravenous line).

 $\mathsf{DBL^{TM}}$  Meropenem for Injection can be given either:

- as a slow injection over approximately 5 minutes directly into the vein, or
- as a slow drip over 15 to 30 minutes.

Your doctor will decide which is best for

### How much will you be given

Your doctor will decide what dose of DBL<sup>TM</sup> Meropenem for Injection you will need depending on certain factors such as your type of infection and your age. The usual dose is 500mg to 1g injected every 8 hours.

If you have meningitis you may require more, while a lower dose may be used for children or if you have kidney problems.

#### How long it is given it for

DBL<sup>TM</sup> Meropenem for Injection needs to be given as a series of injections over a few days. Your doctor will decide how many days you will need to have DBL<sup>TM</sup> Meropenem for Injection for.

If you take too much (overdose)

As DBL<sup>TM</sup> Meropenem for Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given DBL<sup>TM</sup> Meropenem for Injection, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand)

While you are using DBL™ Meropenem for Injection.

### Things you must do

If you develop severe diarrhoea, tell your doctor, nurse or pharmacist immediately. Do this even if it occurs several weeks after you have been given DBL<sup>TM</sup> Meropenem for Injection.

It may mean that you have a serious bowel condition and you may need urgent medical

If you are about to have any blood tests, tell your doctor that you are being treated with this medicine.

It may interfere with the results of some tests.

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

### Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking  $DBL^{TM}$  Meropenem for Injection.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- Pain, swelling or redness around the injection site
- nausea and vomiting
- headache
- diarrhoea
- · abdominal pain
- Any symptoms involving the skin e.g. itching or a rash

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- severe diarrhoea, even if it occurs several weeks after you have been given DBL<sup>TM</sup> Meropenem for Injection
- Convulsions / seizures (fits)
- allergic reactions symptoms 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

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

DBL<sup>TM</sup> Meropenem for Injection may affect your liver and should be monitored by your doctor.

Occasionally, DBL<sup>TM</sup> Meropenem for Injection may be associated with changes in your blood that may require your doctor to do certain blood tests. Tell your doctor if you need to control your salt intake.

## Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Caution should be taken before driving or operating machines and take into account how DBL<sup>TM</sup> Meropenem for Injection may affect you.

## After using DBL™ Meropenem for Injection

### Storage

The hospital staff will store DBL<sup>TM</sup> Meropenem for Injection in a safe place at a temperature below 25°C. They will also check that the expiry date has not passed.

### Disposal

The hospital staff will dispose of any unused DBL<sup>TM</sup> Meropenem for Injection.

### Product description

### What it looks like

DBL<sup>TM</sup> Meropenem for Injection comes as a sterile white powder in a glass vial. The hospital staff then makes it into a solution ready for intravenous use.

### Ingredients

### Active ingredient

DBL<sup>TM</sup> Meropenem for Injection contains either 500mg or 1g of meropenem (as the trihydrate form) as the active ingredient.

### **Inactive ingredient**

DBL<sup>TM</sup> Meropenem for Injection also contains:

· sodium carbonate

DBL<sup>TM</sup> Meropenem for Injection contains no preservative.

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

### Sponsor

DBL<sup>TM</sup> Meropenem for Injection is supplied by:

### **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 DBL<sup>TM</sup> Meropenem for Injection is

DBL<sup>TM</sup> Meropenem for Injection is available in the following strengths:

• 500mg/vial: AUST R 161446

• 1g/vial: AUST R 161447

This leaflet was produced in March 2016.