APPROVED PATIENT INFORMATION LEAFLET

DORIBAX® 500 mg

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

DORIBAX® 500 mg Powder for solution for injection

Read all of this leaflet carefully before you receive DORIBAX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DORIBAX® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT DORIBAX® CONTAINS

The active substance in DORIBAX® is doripenem.

DORIBAX® contains 500 mg of doripenem powder, sterile per vial.

DORIBAX® contains no other inactive ingredients.

WHAT DORIBAX® IS USED FOR

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

DORIBAX® is used for the following infections:

- Pneumonia (a serious type of chest or lung infection) that you get in a hospital or similar setting
- Complicated infections of the area around your stomach (abdominal infections).
- Complicated urinary tract infections, including kidney infections.

BEFORE YOU ARE ADMINISTERED DORIBAX®

You should not receive DORIBAX®

- If you are allergic (hypersensitive) to doripenem
- If you are allergic to other antibiotics such as penicillins, cephalosporins or carbapenems (which are used to treat various infections) as you may also be allergic to DORIBAX®.

You should not receive DORIBAX® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before being given DORIBAX®.

Take special care with DORIBAX®:

If you have:

- Kidney disease. Your doctor may need to reduce your dose of DORIBAX®.
- Allergies to any medicines, including antibiotics.
- Colitis (severe diarrhoea with inflammation of the large intestine) or any other gastrointestinal disease. It is important that you tell your doctor if you have bloody diarrhoea before, during or after your treatment with DORIBAX®. 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.**

Convulsions have frequently 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.

Tell your doctor if you are taking medicines called valproic acid or sodium valproate (see *Taking other medicines below)*.

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

DORIBAX® should not be given to children or adolescents (under 18 years of age) as there is not enough information to be sure that DORIBAX® can be used safely in children or adolescents.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while receiving DORIBAX®, please consult your doctor, pharmacist or other healthcare professional for advice.

DORIBAX® has not been studied in pregnant women. DORIBAX® should not be used during pregnancy unless your doctor decides the benefit justifies the potential risk to the foetus.

Breastfeeding

Small amounts of DORIBAX® may pass into breast milk. You should therefore not breastfeed your baby while you are receiving DORIBAX®.

Driving and operating machinery

DORIBAX® is usually given in the hospital, however DORIBAX® is not likely to affect your ability to drive or operate machinery.

Taking other medicines with DORIBAX®:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DORIBAX® with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor if you are taking medicines called valproic acid or sodium valproate (used to treat epilepsy, bipolar disorder, migraines or schizophrenia) or probenecid (used to treat gout or high levels of uric acid in the blood). Your doctor will decide whether you should use DORIBAX® in combination with these other medicines.

HOW DORIBAX® IS GIVEN

- DORIBAX® will be prepared and given to you by a doctor or nurse over one or four hours as an intravenous infusion into one of your veins (this is sometimes known as a “drip”).

How much DORIBAX® is given

- Your doctor will decide how much DORIBAX® you need and for how long

- Your doctor will decide how many days treatment you need. It is very important that you continue to receive DORIBAX® for as long as your doctor prescribes it.
- If you have kidney problems, your doctor may reduce your dose of DORIBAX® to 250 mg given over one or four hours every eight or 12 hours.

Children (< 18 years of age)

There is no experience in children and use of DORIBAX® in children is not recommended.

Elderly

DORIBAX® is well tolerated by most older patients. The recommended dosage of DORIBAX® can be administered in older patients with normal kidney function.

If you take more DORIBAX® than you should:

If you are concerned that you may have been given too much DORIBAX®, contact your doctor or another healthcare professional immediately.

If you miss a dose of DORIBAX®:

If you are concerned that you may have missed a dose, contact your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

DORIBAX® can have side effects. Possible side effects of DORIBAX® and the frequency in which they may occur are listed below:

Frequent:

- Headache
- Rash, itching or hives
- Diarrhoea. Tell your doctor straight away if you get bloody diarrhoea before, during or after your treatment with DORIBAX®.
- Feeling sick (nausea)
- Injection site inflammation where the intravenous infusion (or “drip”) goes into your vein (phlebitis)
- Fungal infections (thrush) in your mouth or vagina

- Increase in the level of some liver enzymes in your blood

Less frequent

- Sudden swelling of your lips, face, throat or tongue, a rash, swallowing or breathing problems. These may be signs of a severe allergic reaction (anaphylaxis) and may be life-threatening. **Tell your doctor straight away if you get these as you may need urgent medical treatment.**
- Inflammation of the bowel with diarrhoea (*Clostidium difficile* colitis)
- Decrease in blood platelet count
- Decrease of white blood cells which may increase your risk of infections

The following side effect was also seen in a small number of patients:

- Serious skin reactions, with a widespread rash with peeling skin and blisters in the mouth, eyes and genitals (toxic epidermal necrolysis or Stevens-Johnson syndrome).

Not all side effects reported for DORIBAX® are included in this leaflet. Should your general health worsen while taking DORIBAX®, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF DORIBAX®

Do not store above 30 ˚C. KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Do not use this medicine after the expiry date stated on the container.

The first 2 numbers indicate the month; the next 4 numbers indicate the year. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DORIBAX®

DORIBAX® powder for infusion (500 mg) is packaged in 20 ml Type I clear glass vials with 20 mm grey fluororesin-coated elastomeric stopper, and aluminium seal with ivory-coloured plastic flip-off cap.

Vials are packaged in cartons containing 10 vials.

IDENTIFICATION OF DORIBAX®

A white to slightly yellowish off-white sterile crystalline powder.

REGISTRATION NUMBER

43/20.1.1/0647

NAME AND ADDRESS OF REGISTRATION HOLDER

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