PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DORIBAX® 500 mg powder for solution for infusion

Doripenem monohydrate

Sugar free

Read all of this leaflet carefully before you are given DORIBAX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- 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 is in this leaflet

1. What DORIBAX® is and what it is used for
2. What you need to know before you use DORIBAX®.
3. How to use DORIBAX®.
4. Possible side effects
5. How to store DORIBAX®.
6. Contents of the pack and other information

1. What DORIBAX® is and what it 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.

2. What you need to know before you use DORIBAX®

DORIBAX® should not be administered to you:

- If you are hypersensitive (allergic) to doripenem
- If you are allergic to other antibiotics such as penicillin, 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®.

Warnings and precautions

Tell your doctor or health care provider before being given the injection. Special care should be taken with DORIBAX®.

- If you have a kidney disease. Your doctor may need to reduce your dose of DORIBAX®
- When you are allergic to any medicines, including antibiotics
- If you have 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.

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

Tell your doctor if you are taking medicines called valproic acid or sodium valproate.

Children and adolescents

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.

Other medicines and DORIBAX®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before using this medicine.

Pregnancy

DORIBAX® has not been studied in pregnant women. DORIBAX® should not be used during pregnancy.

Breastfeeding

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

Driving and using machines

It is not always possible to predict to what extent DORIBAX® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DORIBAX® affects them.

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

3. How to use DORIBAX®

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with DORIBAX® will last. It is important that you continue to receive DORIBAX® for as long as your doctor prescribes it. If you have the impression that the effect of DORIBAX® is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself DORIBAX® infusion. It will be given to you by a person who is qualified to do so. 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”).

If you have kidney problems, your doctor may reduce your dose of DORIBAX® to 250 mg given over one or four hours every 8 or 12 hours.

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 receive more DORIBAX® than you should

Since a health care provider will administer DORIBAX® he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use DORIBAX®

Since a health care provider will administer DORIBAX® it is unlikely that the dose will be missed.

If you stop using DORIBAX®

Your doctor will decide how many days treatment you need. It is important that you continue to receive DORIBAX® for as long as your doctor prescribes it.

4. Possible side effects

DORIBAX® can have side effects.

Not all side effects reported for DORIBAX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DORIBAX®, please consult your health care provider for advice.

If any of the following happens, stop using DORIBAX® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.
- 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).
- diarrhoea. Tell your doctor straight away if you get bloody diarrhoea before, during or after your treatment with DORIBAX®.

These are all very serious side effects. If you have them, you may have had a serious reaction to DORIBAX®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

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 (*Clostridium difficile* colitis)
- decrease in blood platelet count
- decrease of white blood cells which may increase your risk of infections
- 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).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-

umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DORIBAX®.

5. How to store DORIBAX®

Store all medicines out of reach of children.

Do not store above 30 °C.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DORIBAX® contains

- The active substance is doripenem
- There are no other ingredients

What DORIBAX® looks like and contents of the pack

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 caps.

Vials are packaged in cartons containing 10 vials.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Included in the pack