

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

**MEROPENEM 500 mg FRESENIUS**

**MEROPENEM 1 000 mg FRESENIUS**

**Sterile powder for solution for injection or infusion**

**Sugar free**

**Read all of this leaflet carefully before you are given MEROPENEM FRESENIUS**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

### **What is in this leaflet:**

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

### **1. What MEROPENEM FRESENIUS is and what it is used for**

Meropenem belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections in adults and children, which may occur in the lungs, bladder and kidney, abdomen, skin, brain, female reproductive organs.

MEROPENEM FRESENIUS may be used in the management of neutropenic patients (patients with low levels of white blood cells) with fever that is suspected to be due to a bacterial infection.

MEROPENEM FRESENIUS may be used to treat bacterial infection of the blood which might be associated with one of the infections mentioned above.

For certain infections your doctor may also prescribe an aminoglycoside type of antibiotic.

## **2. What you need to know before you use MEROPENEM FRESENIUS**

### **Do not use MEROPENEM FRESENIUS:**

- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of MEROPENEM FRESENIUS (listed in section 6).
- if you are allergic (hypersensitive) to meropenem or any other carbapenem antibiotic, or any other type of beta-lactam antibiotic such as penicillin, or cephalosporin.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before being given the injection:

- if you have liver problems;
- if you have previously had severe diarrhoea after taking other antibiotics;
- if you have nervous system problems such as brain disorders or fits (seizures) (see “**Possible side effects**”);
- if you have kidney problems or receive dialysis for kidney failure, as your doctor may want to adapt your dose;
- if you have a condition which requires you to monitor your sodium intake, please inform your doctor or nurse.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before MEROPENEM FRESENIUS is administered to you.

You may develop a positive blood test (“Coombs test”) which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.

You may develop signs and symptoms of severe skin reactions (see section 4). If this happens talk to your doctor or nurse immediately so that they can treat the symptoms.

### **Other medicines and MEROPENEM FRESENIUS**

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

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Probenecid (used to treat gout).
- Valproic acid/sodium valproate (used to treat epilepsy). MEROPENEM FRESENIUS should not be used because it may decrease the effect of sodium valproate.
- Anti-coagulants (used to treat or prevent blood clots) taken by mouth.

### **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 healthcare provider for advice before receiving MEROPENEM FRESENIUS.

The safety of MEROPENEM FRESENIUS during pregnancy has not been established.

It is important that you tell your doctor if you are breastfeeding or if you intend to breastfeed before receiving MEROPENEM FRESENIUS. Small amounts of meropenem may pass into the breast milk and it may affect the baby. You should therefore not breastfeed your baby if you have to be treated with MEROPENEM FRESENIUS, or your doctor may decide on another treatment if you continue breastfeeding.

### **Driving and using machines**

MEROPENEM FRESENIUS has been associated with headache and tingling or pricking skin (paraesthesia). Any of these side effects could affect your ability to drive or operate machines.

MEROPENEM FRESENIUS may cause involuntary muscle movements which may cause the person's body to shake rapidly and uncontrollably (convulsions). This is usually accompanied with a loss of consciousness.

Do not drive or use machines if you experience these side effects.

### **MEROPENEM FRESENIUS contains sodium**

MEROPENEM 500 mg FRESENIUS contains approximately 45,13 mg sodium (main component of cooking/table salt) in each vial/bottle. This is equivalent to 2,3 % of the recommended maximum daily dietary intake of sodium for an adult.

MEROPENEM 1 000 mg FRESENIUS contains approximately 90,25 mg sodium (main component of cooking/table salt) in each vial/bottle. This is equivalent to 4,5 % of the recommended maximum daily dietary intake of sodium for an adult.

If you have a condition which requires you to monitor your sodium intake, such as hypertension, please inform your doctor or nurse.

### **3. How to use MEROPENEM FRESENIUS**

You will not be expected to give yourself MEROPENEM FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with MEROPENEM FRESENIUS will last.

### Use in adults

The dose depends on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need. The usual dose for adults is between 500 mg (milligrams) and 1 000 mg (milligrams). You will usually receive a dose every 8 hours. However, you may receive a dose less often if your kidneys do not work very well.

### Use in children and adolescents

The dose for children over 3 months old and up to 12 years of age is based on the age and weight of the child. The usual dose is between 10 mg and 40 mg of MEROPENEM FRESENIUS for each kilogram (kg) that the child weighs. A dose is usually given every 8 hours. Children who weigh over 50 kg will be given an adult dose.

There is no experience in children with renal problems.

Safety and efficacy in babies under 3 months have not been established and MEROPENEM FRESENIUS is therefore not recommended in this age group.

### How MEROPENEM FRESENIUS will be given

MEROPENEM FRESENIUS will be given to you as an injection or infusion into a large vein.

You will not be expected to give yourself MEROPENEM FRESENIUS. It will be given to you by a healthcare provider who is qualified to do so.

Your doctor or nurse will normally give MEROPENEM FRESENIUS to you.

Your injection should not be mixed with or added to solutions that contain other medicines.

The injection may take about 5 minutes or between 15 and 30 minutes.

You should normally have your injections at the same times each day.

**If you use more MEROPENEM FRESENIUS than you should**

Since a healthcare provider will administer MEROPENEM FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you forget to use MEROPENEM FRESENIUS**

Since a healthcare provider will administer MEROPENEM FRESENIUS, it is unlikely that the dose will be missed.

Do not receive a double dose (two injections at the same time) to make up for a forgotten dose.

**If you stop using MEROPENEM FRESENIUS**

Do not stop having MEROPENEM FRESENIUS until your doctor tells you to, because resistant germs will stay behind if you do not complete a course of treatment.

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

**4. Possible side effects**

MEROPENEM FRESENIUS can have side effects.

Not all side effects reported for MEROPENEM FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using MEROPENEM FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

**If any of the following happens, tell your doctor or nurse immediately, as he/she may decide to stop administering MEROPENEM FRESENIUS:**

**Severe allergic reactions:**

The signs may include a sudden onset of:

- Severe rash, itching or hives on the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.
- Serious skin reactions which include:
  - Serious hypersensitivity reactions involving fever, skin rash, and changes in the blood tests that check how the liver is working (increased levels of liver enzymes) and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as DRESS syndrome.
  - Severe red scaly rash, itching, skin bumps that contain pus, blisters or peeling of the skin. This may be associated with a high fever and joint pains.
  - Serious severe skin rashes that can appear as reddish circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome) or a more severe form (toxic epidermal necrolysis).

**Damage to red blood cells:**

The signs include:

- being breathless when you do not expect it
- red or brown urine (haemolytic anaemia).

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

**Tell your doctor if you notice any of the following:**

Frequent side effects

- Abdominal (stomach) pain.
- Diarrhoea.
- Being sick (vomiting).
- Feeling sick (nausea).
- Headache.
- Skin rash, itchy skin.
- Pain and inflammation.
- Increased numbers of platelets in your blood (shown in a blood test).
- Changes in blood tests, including tests that show how well your liver is working.

Less frequent side effects

- Changes in your blood. These include reduced numbers of platelets (which may make you bruise more easily), increased numbers of some white blood cells, decreased numbers of other white cells and increased amounts of a substance called 'bilirubin'.  
Your doctor may do blood tests from time to time.
- Changes in blood tests, including tests that show how well your kidneys are working.
- A tingling feeling (pins and needles).
- Infections of the mouth or the vagina that are caused by a fungus (thrush).
- Delirium (an abrupt change in the brain that causes mental confusion).
- Inflammation of the bowel with diarrhoea.

- Pinpoint, round, red, brown or purple spots that appear on the skin as a result of bleeding.
- Purple spots (blood spots, which occur when small blood vessels burst, causing blood to pool under the skin).
- Sweating.
- Flushing.
- Inflammation of a vein that occurs when a blood clot forms.
- Sore veins where MEROPENEM FRESENIUS is injected.
- Other changes in your blood. The symptoms include frequent infections, high temperature and sore throat (agranulocytosis). Your doctor may do blood tests from time to time.
- Fits (convulsions).

Frequency not known (cannot be estimated from available data)

Increased liver enzymes and a type of white blood cell (eosinophilia), with enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as “DRESS”-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 MEROPENEM FRESENIUS.

You may report any suspected adverse drug reactions to your healthcare provider or the Holder of the Certificate of Registration at the following email address: [safety.fksa@fresenius-kabi.com](mailto:safety.fksa@fresenius-kabi.com) and to the relevant medicine's regulatory authority in the country where the MEROPENEM FRESENIUS is marketed.

## **5. How to store MEROPENEM FRESENIUS**

Store all medicines out of reach of children.

### Dry powder

Store the dry powder at or below 25 °C and protect from light. Keep the vial/bottle in the outer container until required for use.

### Reconstituted Solution

The product must be used immediately after first opening.

Do not freeze the reconstituted solution.

### **Injection**

After reconstitution: The reconstituted solutions for intravenous injection should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous injection should not exceed:

- 3 hours when stored at room temperature up to 25 °C;
- 12 hours when stored under refrigerated conditions (2 – 8 °C).

### **Infusion**

After reconstitution: The reconstituted solutions for intravenous infusion should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed:

- 3 hours when stored at room temperature up to 25 °C when MEROPENEM FRESENIUS is dissolved in sodium chloride;
- 24 hours when stored under refrigerated conditions (2 - 8 °C) when MEROPENEM FRESENIUS is dissolved in sodium chloride;
- 1 hour when stored at room temperature up to 25 °C when MEROPENEM FRESENIUS is dissolved in dextrose solution;
- 8 hours when stored under refrigerated conditions (2 – 8 °C) when MEROPENEM FRESENIUS is dissolved in dextrose solution.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use MEROPENEM FRESENIUS after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

## **6. Contents of the pack and other information**

### **What MEROPENEM FRESENIUS contains**

The active substance is meropenem.

MEROPENEM 500 mg FRESENIUS:

Each 20 mL vial or 100 mL bottle contains 500 mg anhydrous meropenem as meropenem trihydrate.

MEROPENEM 1 000 mg FRESENIUS:

Each 20 mL vial or 100 mL bottle contains 1 000 mg anhydrous meropenem as meropenem trihydrate.

The other ingredient is anhydrous sodium carbonate.

**What MEROPENEM FRESENIUS looks like and contents of the pack**

MEROPENEM FRESENIUS is a white to light yellow powder.

MEROPENEM 500 mg FRESENIUS:

20 mL Type III colourless glass vials or 100 mL Type II colourless glass bottles, closed with bromobutyl rubber stoppers and sealed with 20 mm or 32 mm flip-off plastic-aluminium caps.

MEROPENEM 1 000 mg FRESENIUS:

20 mL Type III colourless glass vials or 100 mL Type II colourless glass bottles, closed with bromobutyl rubber stoppers and sealed with 20 mm or 32 mm flip-off plastic-aluminium caps.

Pack sizes of 1 or 10 vials/bottles.

Not all pack sizes may be marketed.

**Holder of the Certificates of Registration**

Fresenius Kabi SA (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House, Midrand, 1685

SOUTH AFRICA

Tel. +27 (0)11 545 0000

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MEROPENEM 500 mg FRESENIUS: 48/20.1.1/0293

MEROPENEM 1 000 mg FRESENIUS: 48/20.1.1/0294

**Access to the corresponding Professional Information**

The professional information will be printed and supplied with the vial/bottle.