PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MERONEM® 500 Powder for solution for injection or infusion

MERONEM® 1 000 Powder for solution for injection or infusion

Meropenem trihydrate

Sugar free

Read all of this leaflet carefully before you are given MERONEM

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

1. What MERONEM is and what it is used for

MERONEM is available as an injection for intravenous use (into a large vein).

MERONEM belongs to a group of medicines called carbapenem antibiotics. This means that within your body it can kill a wide range of bacteria, which may be the cause of serious infections.

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MERONEM is used to treat infections which may occur in the lungs, bladder and kidneys, abdomen, skin, brain (meningitis), female reproductive organs (including infections which may occur after childbirth) and infections of the blood, which may include the whole body. It is also given to certain patients who have a low resistance to infection and in whom the site of infection may not be known.

2. What you need to know before you use MERONEM

MERONEM should not be administered to you:

- if you are hypersensitive (allergic) to meropenem or any of the other ingredients of MERONEM (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given the injection or infusion:

- if you have ever had an allergic reaction to any other antibiotics including penicillins, other carbapenems or cephalosporins.
- if you are suffering from any disorder or disease which affects your kidneys. Please inform your doctor.
- if you have suffered diarrhoea as a result of taking other antibiotics.

Children

MERONEM is not recommended in children under 3 months of age.

Other medicines and MERONEM

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

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

- probenecid (for gout)

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- antiepileptic agent sodium valproate which may become less effective whilst receiving MERONEM

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, you should not receive MERONEM.

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 taking this medicine.

Driving and using machines

MERONEM is unlikely to affect your ability to drive a car or to operate machinery.

It is not always possible to predict to what extent MERONEM 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 MERONEM affects them.

3. How to use MERONEM

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

The exact dose you are given will be decided by your doctor. It will vary depending on the type of infection you have, where the infection is in the body and the severity of the infection.

Your injection must not be mixed with or added to other solutions containing medicines.

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Your doctor will tell you how long your treatment with MERONEM will last. You should only stop using MERONEM when your doctor tells you. If you have the impression that the effect of MERONEM is too strong or too weak, tell your doctor or pharmacist.

If you receive more MERONEM than you should

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

If you miss a dose of MERONEM

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

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

MERONEM can have side effects.

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

Tell your doctor if you notice any of the following:

- nausea
- vomiting
- diarrhoea
- skin rash
- itchiness
- headache
- tingling
- sore veins where MERONEM is injected

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- fungal infection of the mouth or the vagina
- rare allergic reactions

Very rarely, the use of MERONEM has been associated with damage to red blood cells. Signs of this include unexpected breathlessness and/or red/brown urine and should be reported to your doctor immediately.

MERONEM may be associated with changes in your blood, which may require your doctor to do certain blood tests.

Convulsions have been reported very occasionally although it is not clear if these were caused by MERONEM.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MERONEM.

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5. How to store MERONEM

- Store all medicines out of reach of children.
- Before they are made up, vials should be stored at or below 30 °C.
- Do not freeze.
- Store in the original container.
- Do not use after the expiry date stated on the carton.
- 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 MERONEM contains

- The active substance is meropenem trihydrate. MERONEM 500 contains meropenem anhydrous (as trihydrate) 500 mg/vial. MERONEM 1 000 contains meropenem anhydrous (as trihydrate) 1 000 mg/vial.
- The other ingredient is sodium carbonate.

What MERONEM looks like and contents of the pack

Powder

Clear glass vial containing a white to light yellow powder.

Reconstituted solution

The solution is clear and varies from colourless to yellow depending on the concentration.

MERONEM 500: 20 mL vial in single packs or packs containing 10 vials.

MERONEM 1 000: 30 mL vial in single packs or packs containing 10 vials.

Holder of Certificate of Registration

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This leaflet was last revised in

December 2021

Registration numbers

MERONEM 500: 29/20.1.1/0340

MERONEM 1 000: 29/20.1.1/0341

Viewed on: Monday, July 28, 2025 - 1:21:38 AM Eastern Time