

Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Meropenem Injection I.P.

MERONEM®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Meronem (Meropenem) is and what it is used for
2. What you need to know before you take Meronem (Meropenem)
3. How to take Meronem (Meropenem)
4. Possible side effects
5. How to store Meronem (Meropenem)
6. Contents of the pack and other information

1. What Meronem (Meropenem) is and what it is used for

Meronem (Meropenem) contains the active substance meropenem and belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

Meronem (Meropenem) IV is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem.

- Pneumonias and Nosocomial Pneumonias
- Urinary Tract Infections
- Intra-abdominal Infections
- Gynaecological Infections, such as endometritis and pelvic inflammatory disease.
- Skin and Skin Structure Infections
- Acute bacterial infection of the brain (Meningitis)
- Septicaemia
- Empiric treatment, for presumed infections in adult patients with febrile neutropenia.

Meronem (Meropenem) has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

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2. What you need to know before you take Meronem (Meropenem)

Do not take Meronem (Meropenem)

- If you are allergic (hypersensitive) to meropenem or any of the other ingredients of this medicine (listed in Section 6).
- If you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems as you may also be allergic to Meronem (Meropenem).

Warnings and precautions

Talk to your doctor before using Meronem (Meropenem) if:

- You have health problems, such as liver problems.
- You have had severe diarrhoea after taking other antibiotics.

You may develop a positive 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 immediately so that they can treat the symptoms.

If you are not sure if any of the above applies to you, talk to your doctor before using Meronem (Meropenem).

Other medicines and Meronem (Meropenem)

Tell your doctor if you are taking, have recently taken or might take any other medicines. This is because Meronem (Meropenem) can affect the way some medicines work, and some medicines can have an effect on Meronem (Meropenem).

In particular, tell your doctor if you are taking any of the following medicines:

- Probenecid (used to treat gout).
- Valproic acid/sodium valproate/valpromide (used to treat epilepsy). Meronem should not be used because it may decrease the effect of sodium valproate.
- Oral anti-coagulant agent (used to treat or prevent blood clots).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Meronem (Meropenem) during pregnancy. Your doctor will decide whether you should use Meronem (Meropenem).

It is important that you tell your doctor if you are breast-feeding or if you intend to breast-feed before receiving Meronem (Meropenem). Small amounts of this medicine may pass into the breast milk. Therefore, your doctor will decide whether you should use Meronem (Meropenem) while breast-feeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

Meropenem (Meropenem) 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 (Meropenem) 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 this side effect.

Meropenem (Meropenem) contains sodium

Meropenem 500 mg: This medicine contains 45 mg sodium (main component of cooking/table salt) in each 500 mg dose. This is equivalent to 2.25% of the recommended maximum daily dietary intake of sodium for an adult.

Meropenem 1 g: This medicine contains 90 mg sodium (main component of cooking/table salt) in each 1 g dose. 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 please inform your doctor.

3. How to take Meropenem (Meropenem)

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Use in adults and adolescents

- 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 dose for adults and adolescents is usually between 500 mg (milligrams) and 2 g (gram). 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

- The dose for children over 3 months old and up to 12 years of age is decided using the age and weight of the child. The usual dose is between 10 mg and 40 mg of Meropenem (Meropenem) 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.

Meropenem (Meropenem) will be given to you as an injection or infusion into a large vein.

Your doctor or nurse will normally give Meropenem (Meropenem) to you.

Meropenem (Meropenem) is usually given by intravenous infusion over approximately 15 to 30 minutes. Alternatively, Meropenem (Meropenem) doses of up to 20 mg/kg may be given as an intravenous bolus over approximately 5 minutes. There are limited safety data available to support the administration of a 40 mg/kg dose in children as an intravenous bolus injection.

If you receive more Meropenem (Meropenem) than you should

If you are concerned that you may have been given too much Meropenem (Meropenem), talk to your doctor or nurse immediately.

If you missed a dose of Meronem (Meropenem)

If you are concerned that you may have missed a dose, talk to your doctor or nurse immediately.

If you stop using Meronem (Meropenem)

Do not stop having Meronem (Meropenem) until your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe allergic reactions

If you have any of these signs and symptoms, **tell your doctor or nurse straight away**. You may need urgent medical treatment. The signs and symptoms 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, skin bumps that contain pus, blisters or peeling of skin, which may be associated with a high fever and joint pain.
 - 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).

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Abdominal (stomach) pain.
- Feeling sick (nausea).
- Being sick (vomiting).
- Diarrhoea.
- 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.

Uncommon (may affect up to 1 in 100 people)

- 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 kidney is working.
- A tingling feeling (pins and needles).
- Infections of the mouth or the vagina that are caused by a fungus (thrush).
- Inflammation of the bowel with diarrhoea.
- Sore veins where Meronem (Meropenem) is injected.

Rare (may affect up to 1 in 1,000 people)

- Fits (convulsions).
- Acute disorientation and confusion (delirium).

Sudden chest pain, which may be a sign of a potentially serious allergic reaction called Kounis syndrome has been noted with other medicines of the same type. If this happens talk to a doctor or nurse immediately.

5. How to store Meronem (Meropenem)

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

Do not freeze the reconstituted solution.

Injection

Meronem (Meropenem) to be used for bolus intravenous injection should be constituted with sterile Water for Injections.

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 up to 25°C
- 12 hours when stored under refrigerated conditions (2-8°C).

Infusion

For intravenous infusion Meronem (Meropenem) vials may be directly constituted with 0.9% sodium chloride or 5% dextrose solutions for 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 up to 25°C when Meronem is dissolved in sodium chloride;

- 24 hours when stored under refrigerated conditions (2-8°C) when Meronem is dissolved in sodium chloride;

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

Reconstituted solution of the product in 5% dextrose solution should be used immediately.

6. Contents of the pack and other information

What Meronem contains

The active substance is meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

The active substance is meropenem trihydrate equivalent to 1 g anhydrous meropenem.

The other ingredient is anhydrous sodium carbonate.

What Meronem looks like and contents of the pack

Meronem is a white to light yellow powder for solution for injection or infusion in a clear, type I glass vial with Grey, siliconized, halobutyl rubber stoppers and aluminium crimp seals.

Imported and Marketed by:

Pfizer Limited, The Capital – A Wing, 1802, 18th Floor, Plot No C-70, G Block,

Bandra Kurla Complex, Bandra (East), Mumbai 400 051, India

Manufactured by:

Please refer the outer pack for details.

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