

Package leaflet: Information for the user

Meropenem 0.5 g Powder for solution for injection or infusion

Meropenem 1 g Powder for solution for injection or infusion

Meropenem

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Meropenem infusion is and what it is used for

Meropenem infusion 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.

Meropenem is used to treat the following in adults and children aged 3 months and older:

- Infection affecting the lungs (pneumonia)
- Lung and bronchial infections in patients suffering from cystic fibrosis
- Complicated urinary tract infections
- Complicated infections in the abdomen
- Infections that you can catch during or after the delivery
- Complicated skin and soft tissues infections
- Acute bacterial infection of the brain (meningitis)

Meropenem infusion may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Meropenem infusion may be used to treat bacterial infection of the blood which might be associated with a type of infection mentioned above.

2. What you need to know before you use Meropenem infusion

Do not use Meropenem infusion

- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of Meropenem infusion (listed in section 6 Contents of the pack and other information).
- if you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems as you may also be allergic to meropenem

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Meropenem infusion :

- if you have health problems, such as liver or kidney problems.
- if 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 or nurse 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 or nurse before using Meropenem infusion.

Other medicines and Meropenem infusion

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

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

- Probenecid (used to treat gout).
- Valproic acid/sodium valproate/valpromide (used to treat epilepsy). Meropenem infusion 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 or pharmacist for advice before using this medicine. It is preferable to avoid the use of meropenem during pregnancy.

Your doctor will decide whether you should use Meropenem.

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

Meropenem infusion 0.5 g : This medicinal product contains approximately 45.1 mg of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

Meropenem infusion 1 g: This medicinal product contains approximately 90.2 mg of sodium per 1 g dose which should be taken into consideration by patients on a controlled sodium diet.

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

3. How to use Meropenem infusion

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

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 dose for adults 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 and adolescents

- 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 infusion 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.

How to use Meropenem infusion

- Meropenem infusion will be given to you as an injection or infusion into a large vein.
- Your doctor or nurse will normally give Meropenem infusion to you.
- However, some patients, parents and carers are trained to give Meropenem infusion at home. Instructions for doing this are provided in this leaflet (in the section called 'Instructions for giving Meropenem infusion to yourself or someone else at home'). Always use Meropenem infusion exactly as your doctor has told you. You should check with your doctor if you are not sure.
- 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. Your doctor will tell you how to give Meropenem infusion.
- You should normally have your injections at the same times each day.

If you use more Meropenem infusion than you should

If you accidentally use more than your prescribed dose, contact your doctor or nearest hospital straight away.

If you forget to use Meropenem infusion

If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection.

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

If you stop using Meropenem infusion

Do not stop having Meropenem infusion until your doctor tells you to.

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

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).

Damage to red blood cells (not known)

The signs include:

- Being breathless when you do not expect it.
- Red or brown urine.

If you notice any of the above, **see a doctor straight away.**

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 kidneys are 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 Meropenem infusion is injected.
- Other changes in your blood. The symptoms include frequent infections, high temperature and sore throat. Your doctor may do blood tests from time to time.

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

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the

national reporting system (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt//adrportal

5. How to store Meropenem infusion

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

Do not use this medicine after the expiry date which is stated on the vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After reconstitution: The reconstituted solutions for intravenous injection or infusion should be used immediately. The product should be inspected visually for particulate matter, damage to the container or discolouration (solution should be colourless to pale yellow) prior to administration. Discard the product if such defects are observed.

The time interval between the beginning of reconstitution and the end of intravenous injection or infusion should not exceed one hour.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Meropenem infusion contains

The active substance is meropenem.

Each 500 mg vial contains 500 mg anhydrous meropenem (as meropenem trihydrate).

Each 1 g vial contains 1 g anhydrous meropenem (as meropenem trihydrate).

The other ingredient is sodium carbonate, anhydrous.

What Meropenem infusion looks like and contents of the pack

Meropenem infusion is a white to light yellow powder for solution for injection/infusion in a glass vials. Pack sizes of 1, 5 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,

Euro House,

Euro Business Park,

Little Island, Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the member state	Name of the medicinal product
AT	Meropenem Accord 500 mg Trockenstechampullen Meropenem Accord 1g Trockenstechampullen
BE	Meropenem Accord 500 mg/1 g poeder voor oplossing voor injectie of infusie/ poudre pour solution injectable ou pour perfusion/ Pulver zur Herstellung einer Injektionslösung oder Infusionslösung
BG	Meropenem Accord 1 g powder for solution for injection or infusion
CY	Meropenem Accord 500 mg powder for solution for injection or infusion
CZ	Meropenem Accord
DE	Meropenem Accord 500 mg Pulver zur Herstellung einer Injektions- /Infusionslösung Meropenem Accord 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
DK	Meropenem Accord
EE	Meropenem Accord
ES	Meropenem Accord 500 mg polvo para solución inyectable y para perfusión Meropenem Accord 1 g polvo para solución inyectable y para perfusión
FR	MEROPENEM ACCORD 500 mg, poudre pour solution injectable/pour perfusion MEROPENEM ACCORD 1 g, poudre pour solution injectable/pour perfusion
FI	Meropenem Accord 500 mg injektio-/infuusiokuiva- aine, liuosta varten Meropenem Accord 1 g injektio-/infuusiokuiva-aine , liuosta varten
HU	Meropenem Accord 500 mg por oldatos injekcióhoz vagy infúzióhoz Meropenem Accord 1 g por oldatos injekcióhoz vagy infúzióhoz
IT	Meropenem Accord
LT	Meropenem Accord
LV	Meropenem Accord
MT	Meropenem 0.5 g powder for solution for injection or infusion. Meropenem 1 g powder for solution for injection or infusion.
NL	Meropenem Accord 500 mg, poeder voor oplossing voor
NO	Meropenem Accord
PL	Meropenem Accord
PT	Meropenem Accord
RO	Meropenem Accord 500 mg, pulbere pentru soluție injectabilă / perfuzabilă Meropenem Accord 1 g, pulbere pentru soluție injectabilă / perfuzabilă
SE	Meropenem Accord

SK	Meropeném Accord 500 mg prášok na injekčný alebo infúzny roztok Meropeném Accord 1000 mg prášok na injekčný alebo infúzny roztok
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This leaflet was last revised in 06/2021.

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.