Package leaflet: Information for the user

Meropenem 500 mg powder for solution for injection/infusion
Meropenem 1 g powder for solution for injection/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 is and what it is used for

Meropenem contains the active substance meropenem and belongs to a group of medicinescalled 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 may be used in the management of neutropenic patients with fever that issuspected to be due to a bacterial infection.

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

2. What you need to know before you use Meropenem

Do not use Meropenem:
- if you are allergic to Meropenem or any of the other ingredients of thismedicine (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 meropenem.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Meropenem if:

- you have health problems, such as liver or kidney 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 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.

Liver problems
If you notice yellowing of the skin and eyes, itchy skin, dark-coloured urine or light-coloured stool tell your doctor. This may be a sign of liver problems which your doctor needs to check.

Children
Meropenem is not recommended for use in children less than 3 months old as the safety and efficacy of meropenem in children under 3 months of age have not been established.

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

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 shouldnot 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
Pregnancy
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.

Breastfeeding

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 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.

3. How to use Meropenem

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 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

- Meropenem will be given to you as an injection/infusion into a large vein.
- Your doctor or nurse will normally give Meropenem to you.
- However, some patients, parents and carers are trained to give Meropenem at home.

Instructions for doing this are provided in this leaflet (in the section called 'Instructions for giving Meropenem to yourself or someone else at home'). Always use Meropenem 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.
- You should normally have your injections at the same times each day.

If you use more Meropenem 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

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 have a double dose (two injections at the same time) to make up for a forgotten dose.

If you stop using Meropenem
Do not stop having Meropenem until your doctor tells you to.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist ornurse.

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 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 Meropenem 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.
- Reduced levels of potassium in your blood (which can cause weakness, muscle cramps, tingling and heart rhythm disturbances).
- Liver problems. Yellowing of the skin and eyes, itchy skin, dark-coloured urine or light-coloured stool. If you notice these signs or symptoms, see a doctor straight away.

Rare (may affect up to 1 in 1,000 people)
- Fits (convulsions).
- Acute disorientation and confusion (delirium).

Reporting of side effects
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Meropenem

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 carton and vial label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Injection
After reconstitution:
The reconstituted solutions for intravenous injection should be used immediately.
Chemical and physical in-use stability for a prepared solution for bolus injection has been demonstrated for:
- 3 hours at 25 °C;
- 12 hours under refrigerated conditions (2-8 °C).

Infusion
After reconstitution:
The reconstituted solutions for intravenous infusion should be used immediately.
When Meropenem is dissolved in sodium chloride 0.9% (9 mg/mL), chemical and physical in-use stability for a prepared solution for infusion has been demonstrated for:
- 3 hours when stored at 25 °C;
- 6 hours when stored under refrigerated conditions (2-8 °C);

When Meropenem is dissolved in Glucose 5% (dextrose) (50 mg/mL) the solution shouldbe used immediately.
From a microbiological point of view, unless the method of reconstitution 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 freeze the reconstituted solution.

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

6. Contents of the pack and other information

What Meropenem contains

The active substance is meropenem
Each vial contains meropenem trihydrate equivalent to 500 mg or 1 g meropenem.
The other ingredient is sodium carbonate.

What Meropenem looks like and contents of the pack
Meropenem is a white to pale yellow powder for solution for injection/infusion in a vial.

- **Meropenem 500 mg powder for solution for injection/infusion**

Clear glass vial with bromobutyl rubber stopper sealed with Sky blue aluminum flip off seal.

- **Meropenem 1 g powder for solution for injection/infusion**

Clear glass vial with bromobutyl rubber stopper sealed with Red color aluminum flip off seal.

The medicinal product is supplied in pack sizes of 1 or 10 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Steriscience B.V.
Kranenburgweg 135
2583 ER 'S-Gravenhage
Netherlands

Manufacturer
Pharma Pack Hungary Ltd.
Vasút utca 13.
Budaörs, 2040
Hungary

This medicine is authorised in the Member States of the European Economic Area under the following names:

Netherlands:	Meropenem Steriscience 500 mg, poeder voor oplossingvoor injectie of infusie Meropenem Steriscience 1000 mg, poeder voor oplossingvoor injectie of infusie
Spain:	Meropenem Steriscience 500 mg polvo para soluciónінyectable y para perfusión Meropenem Steriscience 1000 mg polvo para soluciónінyectable y para perfusión
Slovakia:	Meropenem Steriscience 500 mg prášok na injekčný/infúzny roztok Meropenem Steriscience 1000 mg prášok na injekčný/infúzny roztok
Denmark:	Meropenem Steriscience Meropenem Steriscience
France:	Meropenem Steriscience 500 mg poudre pour solutioninjectable/pour perfusion Meropenem Steriscience 1000 mg poudre pour solution injectable/pour perfusion
Belgium:	Meropenem Steriscience 500 mg poeder voor oplossingvoor injectie/infusie Meropenem Steriscience 1000 mg poeder voor oplossing voor injectie/infusie
Hungary:	Meropenem Steriscience,500 mg por oldatos injekcióhoz vagy infúzióhoz Meropenem Steriscience, 1000 mg por oldatos injekcióhoz vagy infúzióhoz
Romania:	Meropenem Steriscience 500 mg pulbere pentru soluţie injectabilă/ perfuzabilă Meropenem Steriscience 1000 mg pulbere pentru soluţie injectabilă/ perfuzabilă
Estonia:	Meropenem Steriscience Meropenem Steriscience
Norway:	Meropenem Steriscience Meropenem Steriscience
Poland:	Meropenem Steriscience Meropenem Steriscience
Czech Republic:	Meropenem Steriscience Meropenem Sterisciencea

Croatia:	Meropenem Steriscience 500 mg prašak za otopinu zainjekciju/infuziju Meropenem Steriscience 1000 mg prašak za otopinu za injekciju/infuziju
Sweden:	Meropenem Steriscience, 500 mg pulver till injektions- /infusionsvätska lösning Meropenem Steriscience, 1000 mg pulver till injektions-/infusionsvätska, lösning
Slovenia:	Meropenem Steriscience 500 mg prašek za raztopino za injiciranje/infundiranje Meropenem Steriscience 1000 mg prašek za raztopino za injiciranje/infundiranje
Latvia:	Meropenem Steriscience, 500 mg pulveris injekciju/infūziju šķīduma pagatavošanai Meropenem Steriscience, 1000 mg pulveris injekciju/infūziju šķīduma pagatavošanai
Cyprus:	Meropenem Steriscience, 500 mg Κόνις για Ενέσιμο Διάλυμα/Εγχυση Meropenem Steriscience, 1000 mg Κόνις για Ενέσιμο Διάλυμα/Εγχυση
Finland:	Meropenem Steriscience 500 mg injektio-/infuusiokuiva- aine liuosta varten Meropenem Steriscience 1000 mg injektio- /infuusiokuiva-aine liuosta varten
Austria:	Meropenem 500 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung Meropenem 1000 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung
Bulgaria:	Меропенем 500 mg прах за инжекционен/инфузионен разтвор Меропенем 1000 mg прах за инжекционен/инфузионен разтвор
Greece:	Meropenem 500 mg κόνις για ενέσιμο διάλυμα / έγχυση Meropenem 1000 mg κόνις για ενέσιμο διάλυμα / έγχυση
Iceland:	Meropenem 500 mg stungulyfs-/innrennslisstofn, lausn Meropenem 1000 mg stungulyfs-/innrennslisstofn, lausn
Ireland:	Meropenem 500 mg powder for solution for injection/infusion Meropenem 1 g powder for solution for injection/infusion
Italy:	Meropenem Steriscience Meropenem Steriscience
Lithuania:	Meropenem 500 mg milteliai injekciniam / infuziniam tirpalui Meropenem 1000 mg milteliai injekciniam / infuziniam tirpalui
Luxembourg:	Meropenem 500 mg Pulver fir Léisung fir Injektioun /Infusioun Meropenem 1000 mg Pulver fir Léisung fir Injektioun / Infusioun
Malta:	Meropenem 500 mg trab għal soluzzjoni għall- injezzjoni/infużjoni Meropenem 1000 mg trab għal soluzzjoni għall-injezzjoni/infużjoni
Portugal:	Meropenem 500 mg pó para solução injetável/perfusão Meropenem 1000 mg pó para solução injetável/perfusão

This leaflet was last revised in 07/2025.

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. 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.

1. 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.

2. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.

3. You should not give antibiotics that were prescribed for you to other people.

4. 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.

The following information is intended for healthcare professionals only:

For full information on posology, warning and precautions, instructions on reconstitution of the medicinal product before administration etc. please refer to Summary of Product Characteristics.

<u>Instructions for giving Meropenem to yourself or someone else at home</u>
Some patients, parents and carers are trained to give Meropenem at home.

Warning – You should only give this medicine to yourself or someone else at home after a doctor or nurse has trained you.

How to prepare this medicine
- The medicine must be mixed with another liquid (the diluent). Your doctor will tell you how much of the diluent to use.

- Use the medicine straight after preparing it. Do not freeze it.

1. Wash your hands and dry them very well. Prepare a clean working area.

2. Remove the Meropenem vial from the packaging. Check the vial and the expiry date.Check that the vial is intact and has not been damaged.

3. Remove the coloured cap and clean the grey rubber stopper with an alcohol wipe. Allow the rubber stopper to dry.

4. Connect a new sterile needle to a new sterile syringe, without touching the ends.

5. Draw up the recommended amount of sterile 'Water for Injections' into the syringe. The amount of liquid that you need is shown in the table below:

Dose of Meropenem	Amount of 'Water for Injections' needed for dilution
500 mg (milligrams)	10 ml (millilitres)
1 g	20 ml
1.5 g	30 ml
2 g	40 ml

Please note: If your prescribed dose of Meropenem is more than 1 g, you will need to use more than 1 vial of Meropenem. You can then draw the liquid in the vials into the one syringe.

6. Put the needle of the syringe through the centre of the grey rubber stopper and inject the recommended amount of Water for Injections into the vial or vials of Meropenem.

7. Remove the needle from the vial and shake the vial well for about 5 seconds, or until all the powder has dissolved. Clean the grey rubber stopper once more with a new alcohol wipe and allow the rubber stopper to dry. The solution should be inspected visually for particles and discolouration prior to administration. Only clear colourless to yellow solution, free from particles should be used.

8. With the plunger of the syringe pushed fully into the syringe, put the needle back through the grey rubber stopper. You must then hold both the syringe and the vial and turn the vial upside down.

9. Keeping the end of the needle in the liquid, pull back the plunger and draw all the liquid in the vial into the syringe.

10. Remove the needle and syringe from the vial and throw the empty vial away in a safe place.

11. Hold the syringe upright, with the needle pointing upwards. Tap the syringe so that any bubbles in the liquid rise to the top of the syringe.

12. Remove any air in the syringe by gently pushing the plunger until all the air has gone.

13. If you are using Meropenem at home, dispose of any needles and infusion lines that you have used in an appropriate way. If your doctor decides to stop your treatment, dispose of any unused

Meropenem in an appropriate way.

Giving the injection
You can either give this medicine through a short cannula or venflon, or through a port or central line.

Giving Meropenem through a short cannula or venflon
1. Remove the needle from the syringe and throw the needle away carefully in your sharps bin.
2. Wipe the end of the short cannula or venflon with an alcohol wipe and allow it to dry. Open the cap on your cannula and connect the syringe.
3. Slowly push the plunger of the syringe to give the antibiotic steadily over about 5 minutes.
4. Once you have finished giving the antibiotic and the syringe is empty, remove the syringe and use a flush as recommended by your doctor or nurse.
5. Close the cap of your cannula and carefully throw the syringe away in your sharps bin.

Giving Meropenem through a port or central line
1. Remove the cap on the port or line, clean the end of the line with an alcohol wipe and allow it to dry.
2. Connect the syringe and slowly push the plunger on the syringe to give the antibiotic steadily over about 5 minutes.
3. Once you have finished giving the antibiotic, remove the syringe and use a flush as recommended by your doctor or nurse.
4. Place a new clean cap on your central line and carefully throw the syringe away in your sharps bin.

Each vial is for single use only.

The solution should be shaken before use. The solutions should be inspected visually for particles and discolouration prior to administration. Only clear colourless to yellow solution, free from particles should be used.
For storage conditions after reconstitution/dilution of the medicinal product, see section 5.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.