Package leaflet: Information for the user

Meropenem STADA 500 mg powder for solution for injection or infusion
Meropenem STADA 1,000 mg powder for solution for injection or infusion

meropenem

Read all of this leaflet carefully before you start taking 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 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 <Invented name> is and what it is used for

<Invented name> belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

- 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)

<Invented name> may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

2. What you need to know before you use <Invented name>

DO NOT use <Invented name>

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

Warnings and precautions
Talk to your doctor or pharmacist before using <Invented name>:
- 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.

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.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using <Invented name>.

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

In particular, tell your doctor or nurse if you are taking any of the following medicines:
- Probenecid (used to treat gout).
- Sodium valproate (used to treat epilepsy). <Invented name> should not be used because it may decrease the effect of sodium valproate.
- Warfarin (medicines that prevent blood clots) blood tests may need to be taken more often.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking 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 and it may affect the baby. 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.

<Invented name> contains sodium
<Invented name> 500 mg: This medicine contains approximately 45 mg sodium (main component of cooking/table salt) in each 500 mg vial. This is equivalent to 2.3 % of the recommended maximum daily dietary intake of sodium for an adult.

<Invented name> 1,000 mg: This medicine contains approximately 90 mg sodium per 1,000 mg vial. This is equivalent to 4.5 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use <Invented name>

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 2,000 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 decided using the age and weight of the child. The usual dose is between 10 mg and 40 mg of <Invented name> 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.
- <Invented name> will be given to you as an injection or infusion into a large vein.
- Your doctor or nurse will normally give <Invented name> to you.
- However, some patients, parents and carers are trained to give <Invented name> at home. Instructions for doing this are provided in this leaflet (in the section called 'Instructions for giving <Invented name> to yourself or someone else at home'). Always use <Invented name> 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 <Invented name>.
- You should normally have your injections at the same times each day.

If you use more <Invented name> 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 <Invented name>

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

Do not stop having <Invented name> until your doctor tells you to.
If you have any further questions on the use of this medicine, ask your doctor 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 a severe allergic reaction, **stop having <Invented name> and see a doctor straight away**. You may need urgent medical treatment. 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.

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**.

DRESS syndrome (not known)
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.
If you notice any of the above, **see a doctor straight away**.

Liver problems
Yellowing of the skin and eyes, itchy skin, dark-coloured urine or light-coloured stool (uncommon: may affect up to 1 in 100 people).
If you notice these signs or symptoms, **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).

- Reduced levels of potassium in your blood (which can cause weakness, muscle cramps, tingling and heart rhythm disturbances).

Rare (may affect up to 1 in 1,000 people)
- Fits (convulsions).

Not known (frequency cannot be estimated from the available data)
- Inflammation of the bowel with diarrhoea.
- Sore veins where <Invented name> 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.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains.

Reporting of side effects
If you get any side effects, talk to your doctor, 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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Prior to reconstitution or dilution, this medicinal product does not require any special storage conditions.

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

Do not use <Invented name> after the expiry date which is stated on the vial label and carton. The expiry date refers to the last day of that month.

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

Do not freeze the reconstituted solution
The solutions should be inspected visually for particles prior to administration. Only clear pale yellow solution, free from visible particles should be used.

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 protect the environment.

6. Contents of the pack and other information

What <invented name> contains:

Each vial of <Invented name> 500 mg powder for solution for injection or infusion contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.
Each vial of <Invented name> 1,000 mg powder for solution for injection or infusion contains meropenem trihydrate equivalent to 1,000 mg anhydrous meropenem.
The other ingredient is sodium carbonate.

What <invented name> looks like and contents of the pack:
<invented name> is a white to light yellow crystalline powder for solution for injection or infusion in vial. Pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The marking authorisation holder is:
[to be completed nationally]
{Name and address}
<{tel}
<{fax}>
<{e-mail}>

The manufacturer is:
[to be completed nationally]
{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:
[to be completed nationally]

This leaflet was last revised in 7 August 2025.
<[To be completed nationally]>

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.

[To be completed nationally]

The following information is intended for medical or healthcare professionals only:

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

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

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

How to prepare this medicine

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

2. Remove the <Invented name> bottle (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 <Invented name>	Amount of 'Water for Injections' needed for dilution
500 mg (milligrams)	10 ml (milliliters)
1,000 mg	20 ml
1,500 mg	30 ml
2,000 mg	40 ml

Please note: If your prescribed dose of <Invented name> is more than 1,000mg, you will need to use more than 1 vial of <Invented name>. 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 <Invented name>.

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.

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 <Invented name> 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 <Invented name> 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 <Invented name> 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 <Invented name> 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.

Giving <Invented name> by intravenous infusion

Meropenem can be given by intravenous infusion over approximately 15 to 30 minutes. For intravenous infusion, <Invented Name> vials can be constituted with sterile water for injection or 0.9 % sodium chloride or 5% glucose solutions for infusion. The solution formed will be further diluted with 0.9 % sodium chloride or 5% glucose solutions (concentration ranging from 1 to 20 mg/mL).

Shake well until dissolved completely. The solutions should be inspected visually for particles prior to administration. Only clear pale yellow solution, free from visible particles should be used.
Each vial is for single use only.