

Package leaflet: Information for the user

Meropenem Aurobindo 500 mg powder for solution for injection or infusion Meropenem Aurobindo 1 g 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

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

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

Meropenem Aurobindo 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 take Meropenem Aurobindo

Do not take Meropenem Aurobindo

- 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, pharmacist or nurse before taking Meropenem Aurobindo.

- 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 Aurobindo.

Other medicines and Meropenem Aurobindo

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

This is because Meropenem Aurobindo can affect the way some medicines work and some medicines can have an effect on Meropenem Aurobindo.

In particular, tell your doctor 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 Aurobindo 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, breast-feeding and fertility

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. 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. However, Meropenem has been associated with headache; tingling or pricking skin (paraesthesia). Any of these side effects could affect your ability to drive or operate machines.

Meropenem may cause and 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.

The maximum recommended daily dose of this medicinal product contains 540 mg sodium (found in table salt). This is equivalent to 27% of the adult recommended maximum daily dietary intake for sodium.

Meropenem Aurobindo 500 mg

Talk to your doctor if you need 9 or more vials daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Meropenem Aurobindo 1 g

Talk to your doctor if you need 5 or more vials daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Meropenem Aurobindo

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor 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 Aurobindo 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 Aurobindo

- Meropenem Aurobindo will be given to you as an injection or infusion into a large vein.
- Your doctor or nurse will normally give Meropenem Aurobindo to you.
- However, some patients, parents and carers are trained to give Meropenem Aurobindo at home. Instructions for doing this are provided in this leaflet (in the section called 'Instructions for giving Meropenem Aurobindo to yourself or someone else at home'). Always use Meropenem Aurobindo 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 Aurobindo.
- You should normally have your injections at the same times each day.

If you take more Meropenem Aurobindo than you should

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

If you forget to take Meropenem Aurobindo

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 taking Meropenem Aurobindo

Do not stop having Meropenem Aurobindo 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 Meropenem Aurobindo 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.
- 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 Aurobindo 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Meropenem Aurobindo

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

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

The medicinal product does not require any special storage condition.

Injection

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 controlled room temperature (15-25°C);
- 8 hours when stored under refrigerated conditions (2-8°C);

Do not freeze the reconstituted solution.

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:

- 6 hours when stored at controlled room temperature (15-25°C) when meropenem is dissolved in sodium chloride;
- 12 hours when stored at 2-8°C when meropenem is dissolved in sodium chloride. In this case, the prepared solution if stored under refrigeration (i.e. 2-8°C) should be used within 1 hour after it has left the refrigerator.

- 30 minutes when meropenem is dissolved in glucose (dextrose).

From a microbiological point of view, unless the method of opening/reconstitution/dilution 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 waste water or house hold 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 Meropenem Aurobindo contains

- The active ingredient is meropenem.

Each vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

Each vial contains meropenem trihydrate equivalent to 1 g anhydrous meropenem.

- The other ingredient is sodium carbonate, anhydrous.

What Meropenem Aurobindo looks like and contents of the pack

Meropenem Aurobindo is a white to pale yellow crystalline powder for solution for injection or infusion in vial.

Product after reconstitution is clear colourless to yellow solution.

Meropenem Aurobindo 500 mg:

674.78 mg powder in a 30ml Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminum seals having taxim blue colour polypropylene discs).

Meropenem Aurobindo 1 g:

1349.56 mg powder in a 40ml Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminum seals having white colour polypropylene discs).

The medicinal product is supplied in pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront,
Floriana FRN 1913, Malta

Manufacturer

APL Swift Services (Malta) Limited
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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.

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

Instructions for giving Meropenem Aurobindo to yourself or someone else at home

Some patients, parents and carers are trained to give Meropenem Aurobindo at home.

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

Instruction for inserting the needle into the rubber stopper:

In order to avoid a coring phenomenon of the plug, when inserting the needle into the rubber stopper, it is recommended to use a needle with a 21-gauge or smaller diameter needle for the reconstitution of the product.

Needle should be inserted only at the center of the rubber stopper, in vertical direction.

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 Aurobindo 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 Meropenem Aurobindo	Amount of 'Water for Injections' needed for dilution
0.5 g (gram)	10 ml (millilitres)
1 g (gram)	20 ml (millilitres)

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 Aurobindo.
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 Meropenem Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo 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.