Package leaflet: Information for the user

Meropenem 1000 mg powder and solvent for solution for 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.
- 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 is an antibiotic used in adults and children aged 3 months and older. It works by killing bacteria that cause infections. It belongs to a group of medicines called carbapenem antibiotics.

Meropenem is used to treat:

- 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 is suspected to be due to a bacterial infection.

Meropenem 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 are given Meropenem

You must not be given Meropenem if:

- you are allergic (hypersensitive) to meropenem or any of the other ingredients (listed in section 6).
- 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 receiving Meropenem if:
- you have health problems, such as liver or kidney problems.
- 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.
- 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 or pharmacist 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, pharmacist 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, pharmacist or nurse before using Meropenem.

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 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 are planning to have a baby, ask your doctor 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.
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

This medicinal product contains 290 mg sodium (main component of cooking/table salt) per bag, equivalent to 14.5 % 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 or pharmacist.

3. How Meropenem is given

Meropenem is usually given by a doctor or nurse as a drip (intravenous infusion) directly into a vein.

The usual dose
The correct dose of meropenem for you will be decided by your doctor and depends on the severity and type of infection, whether you are on any other antibiotics; your weight and age; how well your kidneys are working.

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 (milligrams) 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.

Adults
The dose for adults is usually between 500 mg and 2000 mg. You will usually receive a dose every 8 hours.

Patients with kidney problems
If you have a kidney problem, your doctor may change your dose. Talk to your doctor if this applies to you.

How to use Meropenem
- Meropenem must be reconstituted before administration.
- Your doctor or nurse will normally give Meropenem to you.
- However, some patients, parents and careers are trained to give Meropenem at home. Instructions for doing this are provided at the end of this leaflet (see 'Instructions for giving Meropenem to yourself or someone else at home' in section "The following information is intended for medical or healthcare professionals only").
  Always use Meropenem exactly as your doctor has told you. You should check with your doctor if you are not sure.
- Your infusion should not be mixed with or added to solutions that contain other medicines.
- The infusion may take about 15 and 30 minutes. Your doctor will tell you how to give Meropenem.
- You should normally have your infusions 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 infusion, you should have it as soon as possible. However, if it is almost time for your next infusion, skip the missed infusion. Do not have a double dose (two infusions 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 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 pains.
    - 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
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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 bag. The expiry date refers to the last day of that month.

Do not store above 30 °C.

The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed:
- 3 hours when stored at room temperature (25°C)
- 24 hours when stored under refrigerated conditions (2 – 8 °C)

From a microbiological point of view, unless the method of opening and reconstitution precludes the risk of microbial contamination, the product should be used immediately.

The reconstituted drug product is intended for single use only.
Do not freeze the reconstituted solution.

6. Contents of the pack and other information

What Meropenem contains

The active substance is meropenem.

One two-chamber bag contains meropenem trihydrate equivalent to 1000 mg anhydrous meropenem.

The other ingredients are sodium chloride, water for injections and sodium carbonate.

What Meropenem looks like and contents of the pack

Meropenem is provided in colourless multilayer plastic two-chamber bags with a set-port. One side is opaque, the other side is transparent.
Before reconstitution, Meropenem contains a white to light yellow powder in one chamber and 50 ml of a clear and colourless sodium chloride solution in the other chamber.
After reconstitution, the chamber contains a clear and colourless solution for infusion.

Meropenem is supplied as packs containing 24 two-chamber bags.

Marketing Authorisation Holder

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Postal address:
34209 Melsungen
Germany

Phone: +49-5661-71-0
Fax: +49-5661-71-4567

Manufacturer
ACS Dobfar S.p.A.
Nucleo Industriale S. Atto
64100 Teramo (TE)
ITALY

This leaflet was last revised in 06/2025

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

Posology
The tables below provide general recommendations for dosing.

The dose of meropenem administered and the duration of treatment should take into account the type of infection to be treated, including its severity, and the clinical response.

A dose of up to 2000 mg three times daily in adults and adolescents and a dose of up to 40 mg/kg three times daily in children may be particularly appropriate when treating some types of infections, such as infections due to less susceptible bacterial species (e.g. *Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter spp.*), or very severe infections.

Additional considerations for dosing are needed when treating patients with renal insufficiency (see further below).

Adults and adolescents

Infection	**Dose to be administered every 8 hours**
Severe pneumonia including hospital and ventilator-associated pneumonia	500 mg or 1000 mg
Broncho-pulmonary infections in cystic fibrosis	2000 mg
Complicated urinary tract infections	500 mg or 1000 mg
Complicated intra-abdominal infections	500 mg or 1000 mg
Intra- and post-partum infections	500 mg or 1000 mg
Complicated skin and soft tissue infections	500 mg or 1000 mg
Acute bacterial meningitis	2000 mg
Management of febrile neutropenic patients	1000 mg

Meropenem is usually given by intravenous infusion over approximately 15 to 30 minutes.

Renal impairment
The dose for adults and adolescents should be adjusted when creatinine clearance is less than 51 ml/min, as shown below. There are limited data to support the administration of these dose adjustments for a unit dose of 2000 mg.

Creatinine clearance (ml/min)	**Dose (based on "unit" dose range of 500 mg or 1000 mg or 2000 mg, see table above)**	**Frequency**
26 - 50	one unit dose	every 12 hours
10 - 25	half of one unit dose	every 12 hours
< 10	half of one unit dose	every 24 hours

Meropenem is cleared by haemodialysis and haemofiltration. The required dose should be administered after completion of the haemodialysis cycle.
There are no established dose recommendations for patients receiving peritoneal dialysis.

Hepatic impairment
No dose adjustment is necessary in patients with hepatic impairment.

Dose in elderly patients
No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min.

Paediatric population

Children under 3 months of age
The safety and efficacy of meropenem in children under 3 months of age have not been established and the optimal dose regimen has not been identified. However, limited pharmacokinetic data suggest that 20 mg/kg every 8 hours may be an appropriate regimen.

Children from 3 months to 11 years of age and up to 50 kg body weight
The recommended dose regimens are shown in the table below:

Infection	**Dose to be administered every 8 hours**
Severe pneumonia including hospital and ventilator-associated pneumonia	10 or 20 mg/kg
Broncho-pulmonary infections in cystic fibrosis	40 mg/kg
Complicated urinary tract infections	10 or 20 mg/kg
Complicated intra-abdominal infections	10 or 20 mg/kg
Complicated skin and soft tissue infections	10 mg or 20 mg
Acute bacterial meningitis	40 mg/kg

Management of febrile neutropenic patients	20 mg/kg

Children over 50 kg body weight
The adult dose should be administered.
There is no experience in children with renal impairment.

Method of administration
Intravenous Infusion
Meropenem is usually given by intravenous infusion over approximately 15 to 30 minutes.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life after reconstitution
The reconstituted drug product is intended for single use only.

Chemical and physical in-use stability has been demonstrated for 3 hours at 25 °C or for 24 hours at 2 – 8 °C. From a microbiological point of view, unless the method of opening and reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Shelf life after first opening
The opened two-chamber bag should be used immediately.

Special precautions for disposal and other handling
Do not cover any portion of foil strip with patient label.
Do not use in series connection.
Discard unit if foil strip of container is damaged.
Peel foil strip only when ready for use.
Visually inspect medicinal product prior to reconstition. The solution should only be used if it is clear, colourless and practically free from particles.

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

Instructions for giving Meropenem to yourself or someone else at home
Some patients, parents and careers 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.

Instructions for reconstitution of the Meropenem two-chamber bag
1. Unlatch side tab and unfold container (fig. 1).
2. Peel foil strip from drug powder chamber (fig. 2).
3. Fold container just below solvent meniscus and squeeze until seal between solvent and powder pops open (fig. 3).
4. Shake the solvent-powder mixture until the drug powder is completely dissolved.
5. Visually inspect the reconstituted solution for particulate matter. Do not use unless the solution is clear, colourless and practically free from particles.
6. Squeeze folded container just below the solution meniscus to pop the second seal and release liquid into the port (fig. 4).

7. Remove foil tab cover from set port and attach sterile administration set (fig. 5). Hang bag on IV pole.

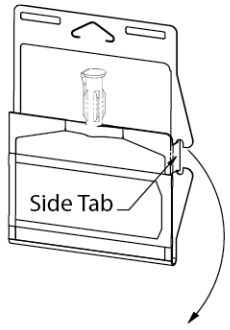

fig. 1

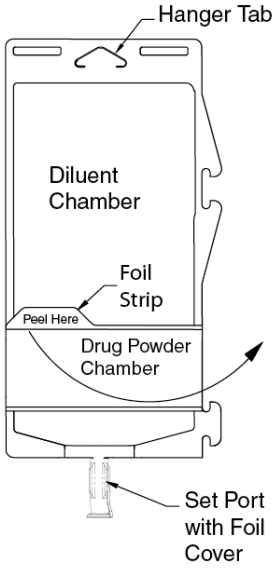

fig. 2

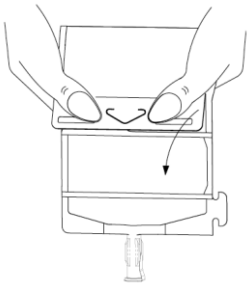

fig. 3

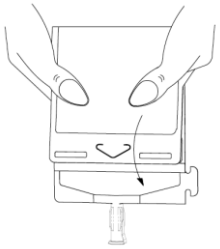

fig. 4

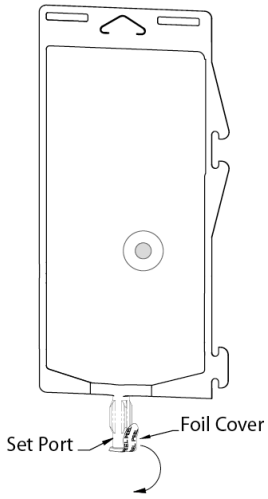

fig. 5