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 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 is and what it is used for

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

This medicine 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).

This medicine may be used in the management of patients with low levels of white blood cells called neutrophils with fever that is suspected to be due to a bacterial infection.

This medicine 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

Do not use Meropenem
- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of this medicine (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 or nurse before using this medicine 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 serious skin reactions (see section 4). If this happens, talk to your doctor or nurse immediately so 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 this medicine.

Other medicines and Meropenem
Tell your doctor 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 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 anticoagulants (medicines taken by mouth 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 for advice before using this medicine.

Pregnancy
It is preferable to avoid the use of meropenem during pregnancy. Your doctor will decide whether you should use it.

Breast-feeding
It is important that you tell your doctor if you are breast-feeding or if you intend to breast-feed before using 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. 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. This medicine 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) per vial. 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) per vial. 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 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 (grams) depending on the type of infection you have. 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 (depending on the severity of the kidney impairment, you will receive a dose every 12 hours or every 24 hours).

Use in children and adolescents
- The dose for children and adolescents over 3 months old and up to 12 years of age is decided depending on the age and weight of the child. The usual dose is between 10 mg and 40 mg of meropenem for each kilogram (kg) of weight of the child. A dose is usually given every 8 hours. Children who weigh over 50 kg will be given an adult dose.

Instructions for use Meropenem
- This medicine will be given to you as an injection or infusion into a large vein.
- Your doctor or nurse will normally give this medicine to you.
- However, some patients, relatives or carers can be trained to give this medicine at home. Instructions for doing this are provided at the end of this leaflet (in the section called 'Instructions for giving Meropenem to yourself or someone else at home').
- 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 or nurse will tell you how to give this medicine.
- Injections should be given 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 go to 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 use 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 this medicine 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 (uncommon)
If you have a severe allergic reaction, **stop having this medicine and seek medical help immediately**. You may need urgent medical treatment. The symptoms of allergic reactions 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 (frequency not known).
- A skin condition (called 'acute generalised exanthematous pustulosis') accompanied by fever, which consists of numerous tiny fluid-filled blisters contained within large areas of swollen and reddened skin (frequency not known).
- 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 (uncommon).
- 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) (uncommon).

Damage to red blood cells (uncommon). The signs include:
- Being breathless when you do not expect it
- Red or brown urine

If you notice any of the above, **seek medical help immediately.**

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 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 this medicine is injected
- 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.
- 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)
- Delirium
- Fits (convulsions)

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

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

This medicine does not require any special storage conditions.

Injection
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 one hour.

Infusion
The reconstituted solution should be diluted immediately after reconstitution. The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed one hour.

Do not freeze the reconstituted solution.

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.

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 Meropenem contains
– The active substance is meropenem.

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

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

– The other ingredient is sodium carbonate.

What Meropenem looks like and contents of the pack
Meropenem is a white to light yellow powder in glass vials. Vials are packed into outer carton.

Pack sizes: 1 or 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder
AS KALCEKS
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Manufacturer
ACS Dobfar S.p.A.
Nucleo Industriale S. Atto (loc. San Nicolò a Tordino)
64100 Teramo (TE), Italy

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

Denmark	Meropenem Kalceks
Austria, Germany	Meropenem Kalceks 500 mg Pulver zur Herstellung einer Injektions-/Infusionslösung Meropenem Kalceks 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Italy, Norway, Sweden	Meropenem Kalceks
Belgium	Meropenem Kalceks 500 mg, 1 g poeder voor oplossing voor injectie/infusie Meropenem Kalceks 500 mg, 1 g poudre pour solution injectable/pour perfusion Meropenem Kalceks 500 mg, 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Croatia	Meropenem Kalceks 500 mg, 1000 mg prašak za otopinu za injekciju/infuziju
Finland	Meropenem Kalceks 500 mg, 1 g injektio-/infuusiokuiva-aine liuosta varten
France	MEROPENEM KALCEKS 500 mg poudre pour solution injectable/pour perfusion MEROPENEM KALCEKS 1 g poudre pour solution injectable/pour perfusion
Hungary	Meropenem Kalceks 500 mg, 1 g por oldatos injekcióhoz vagy infúzióhoz
Ireland	Meropenem 500 mg, 1 g powder for solution for injection/infusion
Latvia	Meropenem Kalceks 500 mg, 1 g pulveris injekciju/infūziju šķīduma pagatavošanai
Lithuania	Meropenem Kalceks 500 mg, 1 g milteliai injekciniam ar infuziniam tirpalui
The Netherlands	Meropenem Kalceks 500 mg, 1 g poeder voor oplossing voor injectie/infusie
Romania	Meropenem Kalceks 500 mg, 1 g pulbere pentru soluţie injectabilă/perfuzabilă
Slovenia	Meropenem Kalceks 500 mg, 1000 mg prašek za raztopino za injiciranje/infundiranje
Slovakia	Meropenem Kalceks 500 mg, 1 g prášok na injekčný/infúzny roztok
Spain	Meropenem Kalceks 500 mg, 1 g polvo para solución inyectable y para perfusión EFG

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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.

- It is very important that you use 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.
- You should not use 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.
- You should not use antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
- You should not give antibiotics that were prescribed for you to other people.
- 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.

Instructions for giving Meropenem to yourself or someone else at home

Some patients, relatives and carers can be trained to give Meropenem at home.

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

Injection
Meropenem to be used for intravenous bolus injection should be reconstituted with sterile 'Water for injections' to the final concentration of 50 mg/ml.
The reconstitution time is not more than 2 minutes.

Infusion
For intravenous infusion vials containing meropenem can be reconstituted directly with sodium chloride 9 mg/ml (0.9 %) solution for infusion or glucose 50 mg/ml (5 %) solution for infusion and diluted with the same diluent to final concentration of 1 to 20 mg/ml.

How to prepare this medicine
- Each vial is for single use only.
- The medicine must not be mixed with another liquids (diluents) except those mentioned above. Your doctor will tell you how much of the diluent to use.
- Use the medicine immediately after preparing it. Do not freeze it.
- Wash your hands and dry them very well. Prepare a clean working area.
- 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.
- Remove the coloured cap and clean the stopper with an alcohol wipe. Allow the stopper to dry.
- Insert a new sterile needle in a new sterile syringe, without touching the ends.
- Draw up the recommended amount of sterile 'Water for injections' and transfer it into the syringe. The amount of liquid (diluent) 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 (gram)	20 ml
1.5 g	30 ml
2 g	40 ml

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

- Put the needle of the syringe through the centre of the vial rubber stopper and inject the recommended amount of 'Water for injections' into the vial or vials of Meropenem.
- Remove the needle from the vial and shake the vial well until all the powder has dissolved (usually it takes no more than 2 minutes). Clean the rubber stopper once more with alcohol and allow the rubber stopper to dry.
- With the plunger of the syringe pushed fully into the syringe, put the needle back through the top of the rubber stopper. You must then hold both the syringe and the vial and turn the vial upside down.
- Keeping the end of the needle in the liquid, pull back the plunger and draw all the liquid in the vial into the syringe.
- Remove the needle and syringe from the vial and throw the empty vial away in a safe place.
- 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.
- Remove any air in the syringe by gently pushing the plunger until all the air has gone.
- If you are using this medicine 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.
- Inspect prepared solution visually prior to administration. Only clear, colourless to yellow solution, free from particles should be used.

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

- Remove the needle from the syringe and throw the needle away carefully in your sharps bin.
- Wipe the end of the short cannula or venflon with alcohol and allow it to dry. Open the cap on your cannula and connect the syringe.
- Slowly push the plunger of the syringe to give the antibiotic steadily over about 5 minutes.
- 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.
- Close the cap of your cannula and carefully throw the syringe away in your sharps bin.

Giving Meropenem through a port or central line

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

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