

Package leaflet: Information for the patient

MEROPENEM MEDIPHA SANTE 500 mg, powder for solution for injection / infusion
MEROPENEM MEDIPHA SANTE 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 Medipha Sante is and what it is used for
2. What you need to know before you use Meropenem Medipha Sante
3. How to use Meropenem Medipha Sante
4. Possible side effects
5. How to store Meropenem Medipha Sante
6. Contents of the pack and other information

1. What Meropenem Medipha Sante is and what it is used for

Meropenem Medipha Sante 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)

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

Meropenem Medipha Sante 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 Medipha Sante

Do not use Meropenem Medipha Sante if

- you are allergic (hypersensitive) to meropenem or any of the other ingredients of Meropenem Medipha Sante (listed in Section 6 Contents of the pack and other information).
- 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 Medipha Sante 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.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using Meropenem Medipha Sante.

Other medicines and Meropenem Medipha Sante

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines.

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

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 Medipha Sante 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 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.

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.

Meropenem Medipha Sante contains sodium.

Meropenem Medipha Sante 500 mg: This medicinal product contains approximately 45 mg of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

Meropenem Medipha Sante 1 g: This medicinal product contains approximately 90 mg of sodium per 1.0 g dose which should be taken into consideration by patients on a controlled sodium diet.

If you have a condition which requires you to monitor your sodium intake please inform your doctor, pharmacist or nurse.

3. How to use Meropenem Medipha Sante

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 Medipha Sante 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 Medipha Sante

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

If you use more Meropenem Medipha Sante 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 Medipha Sante

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 Medipha Sante

Do not stop having Meropenem Medipha Sante 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 a severe allergic reaction, **stop having Meropenem Medipha Sante 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**.

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).

Rare (may affect up to 1 in 1,000 people)

- Fits (convulsions).

Other possible side effects of unknown frequency (frequency cannot be estimated from available data)

- Inflammation of the bowel with diarrhoea.
- Sore veins where Meropenem Medipha Sante 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Meropenem Medipha Sante

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 container after "EXP". The expiry date refers to the last day of that month.

This medicine product does not require any special storage conditions.

After reconstitution: Chemical and physical in-use stability has been demonstrated for 1 hour at 25°C and between 2°C and 8°C. From a microbiological point of view, the product should be used immediately.

Do not freeze the reconstituted solution

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

6. Contents of the pack and other information

What Meropenem Medipha Sante contains

Each vial contains 500 mg meropenem anhydrous (as meropenem trihydrate).

Each vial contains 1 g meropenem anhydrous (as meropenem trihydrate).

The other ingredient is sodium carbonate, anhydrous

What Meropenem Medipha Sante looks like and contents of the pack

This medicine is a white to light yellow powder for solution for injection / infusion in vial. Pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Medipha Sante
Les Fjords – Immeuble Oslo,
19 avenue de Norvège,
91953 COURTABOEUF Cedex,
France.

Manufacturer

IPG Pharma Limited,
Atrium Court,
The Ring,
Bracknell,
Berkshire, RG12 1BW,
United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

FR	MEROPENEM MEDIPHA SANTE 500 mg, poudre pour solution injectable ou pour perfusion MEROPENEM MEDIPHA SANTE 1 g, poudre pour solution injection ou pour perfusion
DE	MEROPENEM MEDIPHA SANTE 500 mg Pulver zur Herstellung einer Injektionslösung oder Infusionslösung MEROPENEM MEDIPHA SANTE 1 g Pulver zur Herstellung einer Injektionslösung oder Infusionslösung
UK	MEROPENEM 500 mg powder for solution for injection or infusion MEROPENEM 1 g powder for solution for injection or infusion
NL	MEROPENEM MEDIPHA SANTE 500 mg Poeder voor oplossing voor injectie of voor intraveneuze infusie MEROPENEM MEDIPHA SANTE 1 g Poeder voor oplossing voor injectie of voor intraveneuze infusie
FI	Meropenem Medipha Sante 500 mg injektio-/infuusiokuiva-aine, liuosta varten Meropenem Medipha Sante 1 g injektio-/infuusiokuiva-aine, liuosta varten
NO	Meropenem Medipha Sante 500 mg pulver til injeksjons- og infusjonsvæske, oppløsning Meropenem Medipha Sante 1 g pulver til injeksjons- og infusjonsvæske, oppløsning
SE	Meropenem Medipha Sante 500 mg Pulver till injektions-/infusionsvätska, lösning Meropenem Medipha Sante 1 g Pulver till injektions-/infusionsvätska, lösning

BE	Meropenem Médipha Santé 500 mg poudre pour solution injectable ou pour perfusion/poeder voor oplossing voor injectie of infusie/Pulver zur Herstellung einer Injektions- oder Infusionslösung Meropenem Médipha Santé 1 g poudre pour solution injectable ou pour perfusion/poeder voor oplossing voor injectie of infusie/Pulver zur Herstellung einer Injektions- oder Infusionslösung
DK	MEROPENEM MEDIPHA SANTE 500 mg pulver til injektions- og infusionsvæske, opløsning MEROPENEM MEDIPHA SANTE 1 g pulver til injektions- og infusionsvæske, opløsning
PL	MEROPENEM MEDIPHA SANTE MEROPENEM MEDIPHA SANTE

This leaflet was last revised in

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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.

Other sources of information

[To be completed nationally]