

Rx Meropenem 500mg & 1g Powder For Solution For Injection Or Infusion

MEROKEM 500MG & 1 G

Package leaflet: Information for the patient

Meropenem 500mg & 1g Powder for solution for Injection or Infusion

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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

1. What Meropenemis and what it is used for
2. What you need to know before you take Abiraterone Acetate
3. How to take Meropenem

4. Possible side effects
5. How to store Meropenem
6. Contents of the pack and other information

1. WHAT MEROPENEM 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.

- 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 delivery
- Complicated skin and soft tissue 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 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 TAKE ABIRATERONE ACETATE

Do not use Meropenem if

- you are allergic to meropenem or any of the other ingredients of Meropenem (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 using Meropenem 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.

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.

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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 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 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 contains sodium

Meropenem 500 mg: This medicine

contains approximately 2.0 mEq of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

Meropenem 1 g: This medicine contains approximately 4.0 mEq of sodium per 1 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 TAKE MEROPENEM

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 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.

Method of administration

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

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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 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 EFFECT

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of possible side effects listed below;

Severe allergic reactions (uncommon: may affect up to 1 in 100 people)

If you have a severe allergic reaction, **stop having Meropenem 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.

Severe reaction (Frequency not known: cannot be estimated from the available data)

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.

Damage to red blood cells (uncommon: may affect up to 1 in 100 people)

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 number 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 MeropenemHospira 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.

Rare: may affect up to 1 in 1,000 people

- Fits (convulsions).

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. By reporting side

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

5. HOW TO STORE ABIRATERONE ACETATE

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 vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

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

After reconstitution: The reconstituted solutions for intravenous injection or infusion should be used immediately. The medicine should be inspected visually for particulate matter, damage to the container or discolouration (solution should be colourless to pale yellow) prior to administration. Discard the medicine if such defects are observed.

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. Do not throw away any medicine 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 FURTHER INFORMATION

What Meropenem contain

Each 0.5 g vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

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

The other ingredient is sodium carbonate, anhydrous.

What Meropenem look like and contents of the pack

Meropenem is a white to pale yellow crystalline powder for solution for injection or infusion in vials. Pack sizes of 1 or 10 vials.



Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

at SURVEY NO. 188/1, 190/1 TO 4,
ATHIYAWAD, DABHEL, DAMAN- 396210
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