

Package leaflet: Information for the patient

Meropenem-Tchaikapharma 1 g powder for solution for injection/infusion (meropenem)

Read all of this leaflet carefully before you are given 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Meropenem-Tchaikapharma is and what it is used for
2. What you need to know before you are given Meropenem-Tchaikapharma
3. How Meropenem-Tchaikapharma is given
4. Possible side effects
5. How to store Meropenem-Tchaikapharma
6. Contents of the pack and other information

1. What Meropenem-Tchaikapharma is and what it is used for

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

2. What you need to know before you are given Meropenem-Tchaikapharma

Do not use Meropenem-Tchaikapharma, if:

- you are allergic (hypersensitive) to meropenem or any of the other ingredients of this medicine (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.

Meropenem-Tchaikapharma is not recommended for children under 3 months of age.

Warnings and precautions

Talk with your doctor, pharmacist or nurse before using Meropenem-Tchaikapharma, 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, pharmacist or nurse before using Meropenem-Tchaikapharma.

Other medicines and Meropenem-Tchaikapharma

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

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

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);
- Oral anticoagulants (used to treat or prevent blood clots).

Pregnancy, breast-feeding and fertility

It is important that you tell your doctor, if you are pregnant or are planning to become pregnant before receiving meropenem. 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 breastfeeding.

Ask your doctor for advice before taking any medicine.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

Meropenem-Tchaikapharma contains sodium

Meropenem-Tchaikapharma 1 g: This medicinal product contains approximately 3,9 mEq 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 Meropenem-Tchaikapharma is given

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. If you are not sure, talk to your doctor, pharmacist or nurse.

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 and 2 g.

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.

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-Tchaikapharma 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 Meropenem-Tchaikapharma is given

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

If you use more Meropenem-Tchaikapharma 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-Tchaikapharma

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 using Meropenem-Tchaikapharma

Do not stop having Meropenem-Tchaikapharma until your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Meropenem-Tchaikapharma can cause side effects, although not everybody gets them.

Severe allergic reactions

If you have a severe allergic reaction, **stop having Meropenem-Tchaikapharma 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 occur in 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 occur in up to 1 in every 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-Tchaikapharma 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 occur in up to 1 in every 1000 people)

- Fits (convulsions).

Not known

Serious hypersensitivity reactions with fever, skin rash and changes in blood tests to check how the liver is working (elevated levels of liver enzymes), and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes These may be signs of dysfunction of many organs, known as DRESS syndrome.

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 national reporting system of Bulgarian Drug Agency. By reporting side effects, you can help provide more information on the safety of this medicine.

Contacts:

Bulgarian Drug Agency.
Bulgaria

8 Damyan Gruev Str.,
1303 Sofia
Tel.: +35 928903417
website: www.bda.bg

5. How to store Meropenem-Tchaikapharma

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Infusion

After reconstitution: The reconstituted solutions for intravenous injection or infusion should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous injection or infusion should not exceed:

- 3 hours when the solution is stored at temperatures up to 25°C;
- 12 hours when the solution is stored under refrigerated conditions (2-8°C).

Infusion

After reconstitution: The reconstituted solutions for intravenous injection or infusion should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous injection or infusion should not exceed:

- 3 hours when the solution is stored at temperatures up to 25°C, when Meropenem-Tchaikapharma is dissolved in sodium chloride solution;
- 24 hours when stored under refrigeration conditions (2-8°C) when Meropenem-Tchaikapharma is dissolved in sodium chloride solution;
- When Meropenem-Tchaikapharma is dissolved in glucose solution, the solution should be used immediately.

From a microbiological point of view, unless the method of opening/dissolving/diluting excludes the risk of microbiological contamination, the product must be used immediately.

If not used immediately, compliance with the terms and conditions of storage is the responsibility of the user.

Do not freeze the reconstituted solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Meropenem-Tchaikapharma contains

The active substance is meropenem. Each vial contains meropenem trihydrate equivalent to 1 g anhydrous meropenem.
The other ingredient is anhydrous sodium carbonate.

What Meropenem-Tchaikapharma looks like and contents of the pack

Meropenem-Tchaikapharma 1 g/vial powder for solution for injection/infusion.

Carton box with 1 or 10 colorless glass vial with rubber stopper, sealed with aluminum cap and patient leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
Tel.: + 359 2 962 54 54
Fax: + 359 2 9603 703
e-mail: info@tchaikapharma.com

For any information about this medicine, please contact the Marketing Authorization Holder.

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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.

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| 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-Tchaikapharma to yourself or someone else at home

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

Warning

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

- 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.

How to prepare this medicine

1. Wash your hands and dry them very well. Prepare a clean working area.
2. Remove the Meropenem-Tchaikapharma 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-Tchaikapharma	Amount of “Water for Injections” needed for dilution
500 mg	10 ml
1 g	20 ml
1.5g	30 ml
2 g	40 ml

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

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-Tchaikapharma.
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-Tchaikapharma 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-Tchaikapharma 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-Tchaikapharma 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-Tchaikapharma 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.