

Meropenem IV APOTEX

Contains the active ingredient meropenem (as trihydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about meropenem. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Meropenem IV APOTEX powder for injection. It contains the active ingredient meropenem trihydrate.

It is used to treat:

- infections of the lungs
- infections of the kidney or bladder (urinary tract infection)
- febrile neutropenia
- infections around the stomach or bowel
- infections of the vagina and womb
- serious skin infections
- infections in the lining of the brain (meningitis)
- infections in the blood stream (septicaemia).

Meropenem is given by injection and is usually only used in hospitals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Meropenem belongs to a group of medicines called carbapenem antibiotics. These medicines work by killing the bacteria that are causing your infection.

Meropenem will not work against fungal or viral infections (such as colds or flu).

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in children under the age of 3 months. Safety and effectiveness in children younger than 3 months have not been established.

Before you are given this medicine

When you must not be given it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, meropenem or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and tell your doctor immediately.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines,
 - any other antibiotics such as other carbapenems, penicillins, cephalosporins or monobactams
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - gastrointestinal or stomach problems, particularly colitis.
 - liver or kidney problems, including dialysis.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with meropenem. These include:

- probenecid - a medicine used to treat gout
- sodium valproate - a medicine used to treat epilepsy or mania.

These medicines may be affected by meropenem or may affect how well it works. If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with meropenem.

How this medicine is given

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much will you be given

Your doctor will decide what dose of meropenem you will need depending on certain factors such as your type of infection and your age. The usual dose is 500mg to 1g injected every 8 hours. If you have meningitis you may require more, while a lower dose may be used for children or if you have kidney problems.

How it is given

Meropenem is injected into your vein. It must always be given by a doctor or nurse.

Many people who get meropenem in hospital will have a drip (intravenous line). Meropenem can be given directly into the vein or the drip without any need for an injection through the skin. It is given either as a slow injection over approximately 5 minutes or as a slow drip over 15 to 30 minutes.

Your doctor will decide which is best for you.

How long will you be given

Your doctor will decide how many days you will need to have meropenem for.

If you take too much (overdose)

If you think that you or anyone else may have been given too much

of this medicine, immediately tell your doctor or nurse.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using this medicine

Things you must do

Tell your doctor that you are using this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell your doctor if you develop severe diarrhoea, even if it occurs several weeks after you have been given meropenem. It may mean that you have a serious bowel condition and you may need urgent medical attention. Do not take any medicine for your diarrhoea without checking with your doctor first.

Your doctor may do tests to monitor your liver function if you have pre-existing liver disorders.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you are given this medicine.

Things to be careful of

Meropenem has been associated with headache, tingling or prickling skin and convulsions / seizures (fits). Any of these could affect your ability to drive or operate machines.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking meropenem or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- pain, swelling or redness around the injection site
- nausea and/or vomiting
- diarrhoea
- skin rash
- itchiness
- tingling, 'pins and needles' sensation.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- severe diarrhoea, even if it occurs several weeks after you have been given meropenem
- convulsions / seizures (fits)
- unexpected breathlessness and/or red/brown urine - this may indicate damage to your red blood cells.

Occasionally, meropenem may be associated with changes in your blood that may require your doctor to do certain blood tests.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to meropenem, do not take any more of this medicine and tell your doctor immediately.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

The hospital staff will store meropenem in a safe place at a temperature below 25°C. They will also check that the expiry date has not passed.

Disposal

The hospital staff will dispose of any unused meropenem.

Product description

What Meropenem IV APOTEX powder for injection or infusion looks like

500mg: white to slightly yellow powder in a 20 mL glass vial

1000mg: white to slightly yellow powder in a 30 mL glass vial

Meropenem vials come in a pack size of 10 vials.

* Not all strengths may be available.

Ingredients

Each vial contains 500mg or 1000mg of meropenem (as trihydrate) as the active ingredient.

It also contains sodium carbonate as the inactive ingredient.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Meropenem IV APOTEX 500mg powder for injection (20 mL glass vial) AUST R 218843

Meropenem IV APOTEX 1000mg powder for injection (30 mL glass vial) AUST R 218840

Sponsor

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