Meropenem-AFT

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Meropenem-AFT?

Meropenem-AFT contains the active ingredient meropenem. Meropenem-AFT is an antibiotic used in adults and children to treat certain serious infections.

For more information, see Section 1. Why am I using Meropenem-AFT? in the full CMI.

2. What should I know before I use Meropenem-AFT?

Do not use if you have ever had an allergic reaction to meropenem or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Meropenem-AFT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Meropenem-AFT and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Meropenem-AFT?

- Your doctor will decide what dose of Meropenem-AFT you will need depending on certain factors such as your type of infection and your age.
- Meropenem-AFT is injected into your vein. It must always be given by a doctor or nurse.

More instructions can be found in Section 4. How do I use Meropenem-AFT? in the full CMI.

5. What should I know while using Meropenem-AFT?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Meropenem-AFT. If you develop severe diarrhoea, tell your doctor, nurse or pharmacist immediately. Do this even if it occurs several weeks after you have been given Meropenem-AFT.
Things you should not do	If you develop diarrhea on being treated with Meropenem-AFT, do not take any medicine for your diarrhoea without checking with your doctor first
Driving or using machines	 This medicine may cause headache, tingling or prickling skin and convulsions / seizures (fits) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything that could be dangerous. Children should be careful when undertaking activities requiring attention such as riding bicycles or climbing
Looking after your medicine	• The hospital staff will store Meropenem-AFT in a safe place at a temperature below 30 °C.

For more information, see Section 5. What should I know while using Meropenem-AFT? in the full CMI.

6. Are there any side effects?

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice allergic reactions, severe diarrhea, convulsions, unexpected breathlessness and/or red/brown urine. Some of the less serious side effects include pain, swelling or redness around the injection site, skin rash or itching, headache, nausea and/or vomiting.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Meropenem-AFT

Active ingredient(s): *meropenem*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Meropenem-AFT. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Meropenem-AFT.

Where to find information in this leaflet:

- 1. Why am I using Meropenem-AFT?
- 2. What should I know before I use Meropenem-AFT?
- 3. What if I am taking other medicines?
- 4. How do I use Meropenem-AFT?
- 5. What should I know while using Meropenem-AFT?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Meropenem-AFT?

Meropenem-AFT contains the active ingredient meropenem. Meropenem-AFT is an antibiotic used in adults and children to treat certain serious infections.

Meropenem-AFT belongs to a group of medicines called carbapenem antibiotics. These medicines work by killing the bacteria that are causing your infection. Meropenem-AFT will not work against fungal or viral infections (such as colds or flu).

Meropenem-AFT is given by injection and is usually only used in hospitals. It is available only with a doctor's prescription.

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

Your doctor may have prescribed it for another reason.

If you are not sure whether you should be given this medicine, talk to your doctor.

Meropenem-AFT is not addictive.

Meropenem-AFT 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.

2. What should I know before I use Meropenem-AFT?

Warnings

Do not use Meropenem-AFT if you are allergic to:

- meropenem, or any of the ingredients listed at the end of this leaflet.
- any other carbopenems, penicillins or other betalactam antibiotics

 Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- · Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

Check with your doctor if you:

- have any other medical conditions like:
 - gastrointestinal or stomach problems, particularly colitis
 - liver problems
 - kidney problems, including dialysis
- have an allergy to any other antibiotics such as other carbapenems, penicillins, cephalosporins or other monobactams.
- Have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Meropenem-AFT should not be used in pregnancy unless the potential benefit justifies the potential risk to the fetus.

Do not breast-feed if you are given this medicine. The active ingredient in Meropenem-AFT passes into breast milk. Your doctor may discuss the risk and benefits if you need this medicine while you are breast feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Meropenem-AFT and affect how it works. 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-AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Meropenem-AFT.

4. How do I use Meropenem-AFT?

How much you will be given

Your doctor will decide what dose of Meropenem-AFT you will need depending on certain factors such as your type of infection and your age. The usual dose is 500 mg to 1 g 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 long you will need to be given Meropenem-AFT

Meropenem-AFT needs to be given as a series of injections over a few days. Your doctor will decide how many days you will need to be given Meropenem-AFT.

How Meropenem-AFT will be given

Meropenem-AFT is injected into your vein.

It must always be given by a doctor or nurse.

Many people who get Meropenem-AFT in hospital will have a drip (intravenous line). Meropenem-AFT 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.

If a dose of Meropenem-AFT is missed

As Meropenem-AFT is given to you under medical supervision, it is very unlikely that a dose will be missed. However, if you feel that a dose has been missed, talk to your doctor or nurse.

If you use too much Meropenem-AFT

As Meropenem-AFT is given to you under medical supervision, it is very unlikely that you will receive too much

However, if you experience any severe side effects after being given Meropenem-AFT, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Meropenem-AFT?

Things you should do

If you develop severe diarrhoea, tell your doctor, nurse or pharmacist immediately. Do this even if it occurs several weeks after you have been given Meropenem-AFT.

It may mean that you have a serious bowel condition and you may need urgent medical attention.

If you are about to have any blood tests, tell your doctor that you are being treated with this medicine.

It may interfere with the results of some tests.

Things you should not do

If you develop diarrhea on being treated with Meropenem-AFT, do not take any medicine for your diarrhoea without checking with your doctor first.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Meropenem-AFT affects you.

This medicine may cause headache, tingling or prickling skin and convulsions / seizures (fits) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything that could be dangerous. Children should be careful when undertaking activities requiring attention such as riding bicycles or climbing.

Looking after your medicine

The hospital staff will store Meropenem-AFT in a safe place at a temperature below 30 °C. They will also check that the expiry date has not passed.

Getting rid of any unwanted medicine

The hospital staff will dispose of any unused Meropenem-AFT.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Meropenem-AFT.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Pain/ skin-related: Pain, swelling or redness around the injection site Skin problem such as rash or itching Headache	Speak to your doctor if you have any of these less serious side effects and they worry you.
Stomach/ digestion - related: Nausea and/ or vomiting Diarrhea	These are more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
Allergy-related: • allergic reactions – symptoms may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. This list includes serious side effects that may require medical attention.
 Heart/Chest-related: chest pain or discomfort fast or irregular heartbeat; or changes in the rhythm or rate of the heartbeat 	
 General body - related: severe diarrhoea, even if it occurs several weeks after you have been given Meropenem-AFT convulsions/ seizures (fits) unexpected breathlessness and/or red/brown urine – this may indicate damage to your red blood cells. muscle discomfort such as swelling, weakness, tender or sore muscles. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Meropenem-AFT contains

Active ingredient	Meropenem trihydrate
(main ingredient)	
Other ingredients	Sodium carbonate
(inactive ingredients)	
Potential allergens	Nil

Do not take this medicine if you are allergic to any of these ingredients.

What Meropenem-AFT looks like

Meropenem-AFT is a sterile white to light yellow powder packed in 20 mL or 30 ml vials. The hospital staff then makes it into a solution ready for intravenous use.

Meropenem-AFT is available in the following strengths and pack sizes:

- 500 mg/ 20 mL vial (Aust R 384155)
- 1000 mg/ 30 mL vial (Aust R 384153)

Who distributes Meropenem-AFT

AFT Pharmaceuticals Pty Ltd.

North Ryde, NSW 2113, Australia customer.service@aftpharm.com

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