

ERTAPENEM KABI

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 being given ERTAPENEM KABI?

ERTAPENEM KABI contains the active ingredient ertapenem. ERTAPENEM KABI is used to treat infections caused by bacteria (germs). These infections include: infections within the abdomen (stomach), pelvic infections, diabetic foot infections in patients without osteomyelitis.

For more information, see Section [1. Why am I being given ERTAPENEM KABI?](#) in the full CMI.

2. What should I know before I am given ERTAPENEM KABI?

You should not be given ERTAPENEM KABI if you have ever had an allergic reaction to ERTAPENEM KABI 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 am given ERTAPENEM KABI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ERTAPENEM KABI 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 be given ERTAPENEM KABI?

ERTAPENEM KABI is given as a slow injection into a vein, known as intravenous infusion.

ERTAPENEM KABI must only be given by a doctor or nurse.

More instructions can be found in Section [4. How will I be given ERTAPENEM KABI?](#) in the full CMI.

5. What should I know while being given ERTAPENEM KABI?

Things you should do	Call your doctor straight away if you: <ul style="list-style-type: none">• Develop severe diarrhoea• Develop a severe skin reaction such as painful red areas, fluid filled bumps, large blisters, or peeling layers of skin whilst being given ERTAPENEM KABI.
Driving or using machines	<ul style="list-style-type: none">• ERTAPENEM KABI may cause dizziness or sleepiness in some patients. Make sure you know how you react to ERTAPENEM KABI before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or sleepy.
Looking after your medicine	<ul style="list-style-type: none">• ERTAPENEM KABI will usually be stored in the pharmacy or on the ward.• The powder for injection should be kept in a cool dry place where the temperature stays before 25°C.

For more information, see Section [5. What should I know while being given ERTAPENEM KABI?](#) in the full CMI.

6. Are there any side effects?

Common side effects of ERTAPENEM KABI include diarrhoea, inflammation of the vein, nausea, and headache.

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.

ERTAPENEM KABI

Active ingredient: *Ertapenem*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ERTAPENEM KABI. **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 ERTAPENEM KABI.**

Where to find information in this leaflet:

- [1. Why am I being given ERTAPENEM KABI?](#)
- [2. What should I know before I am given ERTAPENEM KABI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given ERTAPENEM KABI?](#)
- [5. What should I know while being given ERTAPENEM KABI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given ERTAPENEM KABI?

ERTAPENEM KABI contains the active ingredient ertapenem.

ERTAPENEM KABI belongs to a class of antibiotics called carbapenems. It works by killing the bacteria causing your infection.

ERTAPENEM KABI is used to treat infections caused by bacteria (germs). These infections include:

- Infections within the abdomen (stomach)
- Pelvic infections
- Diabetic foot infections in patients without osteomyelitis.

ERTAPENEM KABI may also be used in patients not responding to, or unable to tolerate, other antibiotics.

Your doctor may have prescribed ERTAPENEM KABI for another reason.

Ask your doctor if you have any questions about why ERTAPENEM KABI has been prescribed for you.

2. What should I know before I am given ERTAPENEM KABI?

Warnings

ERTAPENEM KABI should not be given if:

- you are allergic to ertapenem, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- You have an allergy to other antibiotics in the same class as ERTAPENEM KABI
- You have had a serious allergic reaction (anaphylaxis) to beta-lactam antibiotics, including penicillins or cephalosporins
- The vial cap shows signs of tampering
- The expiry date printed on the pack has passed.

Check with your doctor if you:

- **have any other medical conditions, especially the following:**
 - seizures or fits, or a predisposition to seizures (e.g. brain scarring)
 - kidney disease, or are undergoing dialysis
 - bowel problems while using antibiotics or after finishing them, including severe abdominal or stomach cramps, or watery and severe diarrhoea
- **have allergies to other antibiotics, in particular penicillins and cephalosporins.**
 - If you are allergic to any of them you may be allergic to ERTAPENEM KABI.
- **Are pregnant or intend to become pregnant**
- **Are breastfeeding or intend to breastfeed**
- **Have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
- **Are taking a medicine containing valproic acid**

If you have not told your doctor or any of the above, tell them before you are given ERTAPENEM KABI.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines, the use of ERTAPENEM KABI is generally not recommended during pregnancy. However, if there is a need to consider using ERTAPENEM KABI during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most medicines, the use of ERTAPENEM KABI is generally not recommended while breastfeeding. ERTAPENEM KABI is secreted into human milk.

- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s)

relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

Children

Do not use ERTAPENEM KABI in children under 3 months of age.

The safety and effectiveness in children younger than 3 months of age have not been established.

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 and ERTAPENEM KABI may interfere with each other.

These include:

- **Sodium valproate**, used to control different types of epilepsy and mania

These medicines may be affected by ERTAPENEM KABI or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will decide whether you should use ERTAPENEM KABI in combination with this medicine.

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

4. How will I be given ERTAPENEM KABI?

How is it given

ERTAPENEM KABI is given as a slow injection into a vein, known as intravenous infusion.

ERTAPENEM KABI will be prepared and given to you by a doctor or other healthcare professional.

When is it given

- Your doctor will decide what dose and how long you will receive ERTAPENEM KABI. This depends on your condition and other factors, such as your kidney function. No dose adjustment is necessary if you are elderly.

If you are given too much ERTAPENEM KABI

As this product is administered by a doctor or healthcare professional, it is unlikely you will be given too much ERTAPENEM KABI.

However, if you have any concerns, you should immediately:

- contact a healthcare professional, your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26), 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 being given ERTAPENEM KABI?

Things you should do

Call your doctor straight away if you:

- Develop severe diarrhoea

Do this even if it occurs several weeks after ERTAPENEM KABI has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

This is because antibiotics such as ERTAPENEM KABI can change the type of bacteria in the bowel. As a result, this allows bacteria, normally present in the bowel and normally harmless, to multiply and cause the above symptoms.

Do not take any diarrhoea medicine without first checking with your doctor.

- Develop a severe skin reaction such as painful red areas, fluid filled bumps, large blisters, or peeling layers of skin whilst being given ERTAPENEM KABI. You may need urgent medical care.

Remind any doctor, dentist or pharmacist that you visit that you are using ERTAPENEM KABI.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ERTAPENEM KABI affects you.

ERTAPENEM KABI may cause dizziness or sleepiness in some patients. Make sure you know how you react to ERTAPENEM KABI before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or sleepy.

Looking after your medicine

It is unlikely that you will be asked to store ERTAPENEM KABI yourself. It will usually be stored in the pharmacy on the ward.

Solutions of ERTAPENEM KABI should not be frozen.

Solutions of ERTAPENEM KABI should be used as soon as possible after reconstitution and further dilution. If storage is unavoidable, the solution should be stored in the refrigerator where the temperature is kept between 2°C to 8°C, for not more than 24 hours, and used as soon as practicable within 4 hours after removal from the refrigerator.

As ERTAPENEM KABI does not contain a preservative, there is a risk that any prepared solution that has not been stored in a refrigerator may be contaminated with germs and cause an infection.

Getting rid of any unwanted medicine

A doctor, nurse or pharmacist will dispose of any unused ERTAPENEM KABI.

Any unused vials containing solution of ERTAPENEM KABI which has been prepared, but not used, should be discarded.

Vials of ERTAPENEM KABI are intended for single-use only. They do not contain a preservative and there is a possibility of contamination with repeated use.

6. Are there any side effects?

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.

Common side effects

Common side effects	What to do
<p>Tell your doctor or nurse if you notice any of the following and they worry you:</p> <ul style="list-style-type: none"> • Discomfort of the vein where you had the injection, for example, pain, tenderness, redness, swelling or firm swelling. • Swelling, clotting, tenderness, swelling and inflammation • Headache • Nausea, vomiting • Diarrhoea • Vaginal itching or redness • Alteration in some laboratory blood tests, and a combination of high fever, feeling unwell, and skin rash 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

These are the more common side effects of ERTAPENEM KABI. For the most part, these have been mild.

Rare side effects

Rare side effects	What to do
<p>Tell your doctor or nurse immediately if you notice any of the following:</p> <ul style="list-style-type: none"> • Severe abdominal cramps or stomach cramps • Watery and severe diarrhoea, which may also be bloody • High temperature, also called fever • Seizures or fits • Shortness of breath • Chest pain • Slow heart rate 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these rare side effects.</p>

- Skin rash, redness, itchiness or hives
 - Severe skin reactions, such as painful red areas, fluid-filled bumps, large blisters, or peeling of layers of skin have been reported for the beta-lactam class of antibiotics
 - Formation of lump and warmth at injection site
 - Strange or disturbing thoughts or moods (including agitation, aggression, severe confusion, disorientation, mental status changes)
 - Tremors or uncontrollable twitching, jerking or writhing movements
 - Decreased consciousness
- These may be serious side effects of ERTAPENEM KABI. You may need urgent medical attention. Serious side effects are rare.

Also, tell your doctor if you notice:

- Dizziness, light-headedness, or unsteady walking
- Unusual tiredness or weakness
- Sore, creamy-yellow, raised patches in the mouth (oral thrush)
- Teeth staining

Very rare side effects

Very rare side effects	What to do
<p>A few people may be allergic to some medicines. Tell your doctor or nurse immediately if you notice any of the following. These are examples of acute allergy:</p> <ul style="list-style-type: none"> • Throat or chest tightness, difficulty breathing • Swelling of the mouth, lips, eyes or face • Flushing (sudden redness) of the face • Vomiting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very rare side effects.</p>

If you have these, you may have had a serious allergic reaction to ERTAPENEM KABI. You may need urgent medical attention. These side effects are very rare.

Rare side effects after finishing ERTAPENEM KABI

Who distributes ERTAPENEM KABI

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Telephone: 1300 732 001

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Common side effects	What to do
<p>Tell your doctor or nurse if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with ERTAPENEM KABI:</p> <ul style="list-style-type: none">• Severe abdominal cramps or stomach cramps• Watery and severe diarrhoea, which may also be bloody• Fever, in combination with one or both of the above	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very rare side effects.</p>

These are rare but serious side effects. You may have a serious condition affecting your bowel.

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

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 ERTAPENEM KABI contains

Active ingredient (main ingredient)	Ertapenem 1 g
Other ingredients (inactive ingredients)	Sodium bicarbonate Sodium hydroxide

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

What ERTAPENEM KABI looks like

ERTAPENEM KABI is a sterile, white to yellowish powder in a glass vial. Each vial is packaged within a carton (AUST R 294975).