

Ertapenem Kabi

Ertapenem sodium

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking Ertapenem Kabi against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Ertapenem Kabi is used for

Ertapenem Kabi contains the active ingredient, ertapenem sodium.

Ertapenem is an antibiotic 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 may also be used in patients not responding to, or unable to tolerate, other antibiotics.

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

Your doctor, however, may prescribe Ertapenem Kabi for another purpose.

Ask your doctor if you have any questions about why Ertapenem Kabi has been prescribed for you or your child.

This medicine is not addictive.

Before you are given Ertapenem Kabi

When you or your child must not be given it

Do not use Ertapenem Kabi if:

- **you have an allergy to ertapenem or any of the other ingredients listed at the end of this leaflet.**
you have an allergy to other antibiotics in the same class as ertapenem
- **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.**
If this medicine is used after the expiry date has passed, it may not work.

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.

Before you or your child are given it

Tell the doctor if:

1. you have or have had any 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.

2. you have allergies to other antibiotics, in particular penicillins and cephalosporins.

If you are allergic to any of these you may be allergic to ertapenem.

3. you are pregnant or intend to become pregnant.

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

4. you are breast-feeding or intend to breast-feed.

Like most medicines, the use of ertapenem is generally not recommended while breast-feeding. Ertapenem is secreted into human milk.

5. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

6. you are taking a medicine containing valproic acid or sodium valproate.

If you have not told your doctor about any of the above, tell them before you are given Ertapenem Kabi.

Taking other medicines

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

Some medicines and ertapenem may interfere with each other.

These include:

- sodium valproate (e.g. Epilim®), used to control different types of epilepsy and mania.

This medicine may be affected by ertapenem, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will decide whether you should use ertapenem in combination with this medicine.

Make sure your doctor and pharmacist know about all of the medicines you are taking, as they have more information on medicines to be careful with or avoid while taking ertapenem.

How Ertapenem Kabi is given

Ertapenem Kabi is given as a slow injection into a vein, known as an intravenous infusion.

Ertapenem Kabi must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you or your child 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.

When preparing Ertapenem Kabi for use, it should not be reconstituted or diluted in solutions containing glucose.

Ertapenem Kabi is not compatible with glucose.

If you are given too much (overdose)

If you are concerned that you or your child has received too much Ertapenem Kabi, tell your doctor, nurse or pharmacist immediately.

While you are given Ertapenem Kabi

Things you must do

If you develop severe diarrhoea, tell your doctor, pharmacist or nurse immediately. 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. Do not take any diarrhoea medicine without first checking with your doctor.

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you or your child do not feel well while you are being given Ertapenem Kabi.

Ertapenem helps most people with infection, but it may have unwanted side-effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

While being given it

Tell the doctor or nurse if you notice any of the following and they worry you:

- discomfort of the vein where you had the injection, for example pain, tenderness, redness, swelling or firm swelling sore
- swelling, clotting, tenderness and inflammation
- headache
- nausea or vomiting
- diarrhoea
- vaginal itching or redness
- alterations in some laboratory blood tests, and a combination of high fever, feeling unwell, and skin rash.

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

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

Tell your doctor or nurse immediately if you notice any of the following:

- 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
- skin rash, redness, itchiness or hives
- 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. 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.

These are other side effects that have been reported with ertapenem. These side effects are rare.

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:

- throat or chest tightness, difficulty breathing
- swelling of the mouth, lips, eyes or face
- flushing (sudden redness) of the face
- vomiting

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

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Ertapenem Kabi:

- severe abdominal cramps or stomach cramps

- watery and severe diarrhoea (which may be bloody)
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. This is because antibiotics such as ertapenem 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. Therefore, you may need urgent medical attention. However, this side effect is rare.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Storage

Ertapenem Kabi will usually be stored in the hospital pharmacy or on the ward.

The powder for injection should be kept in a cool dry place where the temperature stays below 25°C.

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.

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.

Product Description

What it looks like

Ertapenem Kabi is a sterile, white to yellowish powder for injection, supplied in a glass vial. Each vial is packaged within a carton.

Ingredients

The active ingredient in Ertapenem Kabi is ertapenem (as sodium). There is 1 g of ertapenem in each vial.

Other ingredients are:

- sodium bicarbonate
- sodium hydroxide.

Supplier

Ertapenem Kabi is supplied in Australia by:

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Telephone: (02) 9391 5555

Ertapenem Kabi is supplied in New Zealand by:

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
Freecall: 0800 144 892

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