

Ertapenem 1 g

powder for concentrate for solution for infusion

ertapenem

Read all of this leaflet carefully before you start using 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, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ertapenem is and what it is used for
2. What you need to know before you take Ertapenem
3. How to take Ertapenem
4. Possible side effects
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1. WHAT ERTAPENEM IS AND WHAT IT IS USED FOR

Ertapenem contains ertapenem which is an antibiotic of the beta-lactam group. It has the ability to kill a wide range of bacteria (germs) that cause infections in various parts of the body.

Ertapenem can be given to persons 3 months of age and older.

Treatment:

Your doctor has prescribed Ertapenem because you or your child has one (or more) of the following types of infection:

- Infection in the abdomen
- Infection affecting the lungs (pneumonia)
- Gynaecological infections
- Skin infections of the foot in diabetic patients.

Prevention:

- Prevention of surgical site infections in adults following surgery of the colon or rectum.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ERTAPENEM

Do not take Ertapenem

- if you are allergic to the active substance (ertapenem) or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to antibiotics such as penicillins, cephalosporins or carbapenems (which are used to treat various infections).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Ertapenem.

During treatment, if you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash), tell your doctor straight away as you may need urgent medical treatment.

While antibiotics including Ertapenem kill certain bacteria, other bacteria and fungi may continue to grow more than normal. This is called overgrowth. Your doctor will monitor you for overgrowth and treat you if necessary.

It is important that you tell your doctor if you have diarrhoea before, during or after your treatment with Ertapenem. This is because you may have a condition known as colitis (an inflammation of the bowel). Do not take any medicine to treat diarrhoea without first checking with your doctor.

Tell your doctor if you are taking medicines called valproic acid or sodium valproate (see Other medicines and Ertapenem).

Tell your doctor about any medical condition you have or have had including:

- Kidney disease. It is particularly important that your doctor knows if you have kidney disease and whether you undergo dialysis treatment.
- Allergies to any medicines, including antibiotics
- Central nervous system disorders, such as localized tremors, or seizures.

Children and adolescents (3 months to 17 years of age)

Experience with Ertapenem is limited in children less than two years of age. In this age group your doctor will decide on the potential benefit of its use. There is no experience in children under 3 months of age.

Other medicines and Ertapenem

Always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription.

Tell your doctor, nurse or pharmacist if you are taking medicines called valproic acid or sodium valproate (used to treat epilepsy, bipolar disorder, migraines, or schizophrenia). This is because Ertapenem can affect the way some other medicines work. Your doctor will decide whether you should use Ertapenem in combination with these other medicines.

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 Ertapenem.

Ertapenem has not been studied in pregnant women. Ertapenem should not be used during pregnancy unless your doctor decides the potential benefit justifies the potential risk to the foetus.

It is important that you tell your doctor if you are breast-feeding or if you intend to breast-feed before receiving Ertapenem.

Women who are receiving Ertapenem should not breast-feed, because it has been found in human milk and the breast-fed baby may therefore be affected.

Driving and using machines

Do not drive or use any tools or machines until you know how you react to the medicine.

Certain side effects, such as dizziness and sleepiness, have been reported with Ertapenem, which may affect some patients' ability to drive or operate machinery.

Ertapenem contains sodium.

This medicine contains approximately 6.0 mEq (approximately 137 mg) of sodium per 1.0 g dose which should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE ERTAPENEM

Ertapenem will always be prepared and given to you intravenously (into a vein) by a doctor or another healthcare professional.

The recommended dose of Ertapenem for adults and adolescents 13 years of age and older is 1 gram (g) given once a day. The recommended dose for children 3 months to 12 years of age is 15 mg/kg given twice daily (not to exceed 1 g/day). Your doctor will decide how many days' treatment you need.

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Ertapenem 1g

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For prevention of surgical site infections following surgery of the colon or rectum, the recommended dose of Ertapenem is 1 g administered as a single intravenous dose 1 hour before surgery.

It is very important that you continue to receive Ertapenem for as long as your doctor prescribes it.

If you take more Ertapenem than you should

If you are concerned that you may have been given too much Ertapenem, contact your doctor or another healthcare professional immediately.

If you miss a dose of Ertapenem

If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Adults 18 years of age and older:

Since the drug has been marketed, severe allergic reactions (anaphylaxis), hypersensitivity syndromes (allergic reactions including rash, fever, abnormal blood tests) have been reported. The first signs of a severe allergic reaction may include swelling of the face and/or throat. If these symptoms occur tell your doctor straight away as you may need urgent medical treatment.

The most common (more than 1 in 100 patients and less than 1 in 10 patients) side effects are:

- Headache

- Diarrhoea, nausea, vomiting
- Rash, itching
- Problems with the vein into which the medicine is given (including inflammation, formation of a lump, swelling at the injection site, or leaking of fluid into the tissue and skin around the injection site)
- Increase in platelet count
- Changes in liver function tests

Less common (more than 1 in 1,000 patients and less than 1 in 100 patients) side effects are:

- Dizziness, sleepiness, sleeplessness, confusion, seizure
- Low blood pressure, slow heart rate
- Shortness of breath, sore throat
- Constipation, yeast infection of the mouth, antibiotic-associated diarrhoea, acid regurgitation, dry mouth, indigestion, loss of appetite
- Skin redness
- Vaginal discharge and irritation
- Abdominal pain, fatigue, fungal infection, fever, oedema/swelling, chest pain, abnormal taste
- Changes in some laboratory blood and urine tests

Side effects reported rarely (more than 1 in 10,000 patients and less than 1 in 1,000 patients) are:

- Decrease in white blood cells, decrease in blood platelet count
- Low blood sugar
- Agitation, anxiety, depression, tremor
- Irregular heart rate, increased blood pressure, bleeding, fast heart rate
- Nasal congestion, cough, bleeding from the nose, pneumonia, abnormal breathing sounds, wheezing
- Inflammation of the gall bladder, difficulty in swallowing, faecal incontinence, jaundice, liver disorder
- Inflammation of the skin, fungal infection of the skin, skin peeling, infection of the wound after an operation
- Muscle cramp, shoulder pain
- Urinary tract infection, kidney impairment
- Miscarriage, genital bleeding
- Allergy, feeling unwell, pelvic peritonitis, changes to the white part of the eye, fainting.

Side effects reported (frequency not known) since the drug has been marketed are:

- Hallucinations
- Decreased consciousness
- Altered mental status (including aggression, delirium, disorientation, mental status changes)
- Abnormal movements
- Muscle weakness
- Unsteady walking
- Teeth staining

There have also been reports of changes in some laboratory blood tests.

Children and adolescents (3 months to 17 years of age):

The most common (more than 1 in 100 patients and less than 1 in 10 patients) side effects are:

- Diarrhoea
- Diaper rash
- Pain at the infusion site
- Changes in white blood cell count
- Changes in liver function tests

Less common (more than 1 in 1,000 patients and less than 1 in 100 patients) side effects are:

- Headache
- Hot flush, high blood pressure, red or purple, flat, pinhead spots under the skin
- Discoloured faeces, black tar-like faeces
- Skin redness, skin rash
- Burning, itching, redness and warmth at infusion site, redness at injection site
- Increase in platelet count
- Changes in some laboratory blood tests

Side effects reported (frequency not known) since the drug has been marketed are:

- Hallucinations
- Altered mental status (including aggression)

Reporting of side effects

If you get any side effects, talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ERTAPENEM

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container and carton after EXP. The first 2 numbers indicate the month; the next 4 numbers indicate the year.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ertapenem contains

The active ingredient of Ertapenem is ertapenem.

Each vial contains 1 g of Ertapenem.

The other ingredients are: Sodium hydrogen carbonate and sodium hydroxide.

What Ertapenem looks like and contents of the pack

Ertapenem is a white to yellowish, freeze-dried powder for concentrate for solution for infusion.

Solutions of Ertapenem range from colourless to pale yellow. Variations of colour within this range do not affect potency.

Ertapenem is supplied in packs of 1 vial or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Hikma Farmacêutica (Portugal) S.A.

Estrada do Rio da Mó, 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal

Manufacturer:

ACS Dobfar S.p.A

Nucleo Industriale S. Atto, S. Nicolò a Tordino, 64100 Teramo, Italy

Distributed by:

Consilient Health (UK) Ltd.

No. 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE

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The following information is intended for medical or healthcare professionals only:

Instructions of how to reconstitute and dilute Ertapenem:

For single use only.

Preparation for intravenous administration:

Ertapenem must be reconstituted and then diluted prior to administration.

Adult and adolescents (13 to 17 years of age) Reconstitution

Reconstitute the contents of a 1 g vial of Ertapenem with 10 ml of water for injection or sodium chloride 9 mg/ml (0.9 %) solution to yield a reconstituted solution of approximately 100 mg/ml.

Shake well to dissolve.

Dilution

For a 50 mL bag of diluent: For a 1 g dose, immediately transfer contents of the reconstituted vial to a 50 ml bag of sodium chloride 9 mg/ml (0.9 %) solution;

or

For a 50 mL vial of diluent: For a 1 g dose, withdraw 10 ml from a 50 ml vial of sodium chloride 9 mg/ml (0.9 %) solution and discard. Transfer the contents of the reconstituted 1 g vial of Ertapenem to the 50 ml vial of sodium chloride 9 mg/ml (0.9 %) solution.

Infusion

Infuse over a period of 30 minutes.

Children (3 months to 12 years of age) Reconstitution

Reconstitute the contents of a 1 g vial of Ertapenem with 10 ml of water for injection or sodium chloride 9 mg/ml (0.9 %) solution to yield a reconstituted solution of approximately 100 mg/ml.

Shake well to dissolve.

Dilution

For a bag of diluent: Transfer a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) to a bag of sodium chloride 9 mg/ml (0.9 %) solution for a final concentration of 20 mg/ml or less; or For a vial of diluent: Transfer a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) to a vial of sodium chloride 9 mg/ml (0.9 %) solution for a final concentration of 20 mg/ml or less.

Infusion

Infuse over a period of 30 minutes.

The reconstituted solution should be diluted in sodium chloride 9 mg/ml (0.9 %) solution immediately after preparation. Chemical and physical in- use stability has been demonstrated for 6 hours at room temperature (25°C) or for 24 hours at 2 to 8°C (in a refrigerator). From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions. Solutions should be used within 4 hours of their removal from the refrigerator. Do not freeze solutions of Ertapenem.

The reconstituted solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever the container permits. Solutions of Ertapenem range from colourless to pale yellow. Variations of colour within this range do not affect potency.

Any unused product or waste material should be disposed of in accordance with local requirements.