Package Leaflet: information for the user

Ertapenem 1 g powder for concentrate for solution for infusion
ertapenem

Read all of this leaflet carefully before you are given 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

This medicine 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.

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.

Ertapenem can also be used for the prevention of surgical site infections in adults following surgery of the colon or rectum.

2. What you need to know before you are given Ertapenem

Do not take Ertapenem
- if you are **allergic to 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 taking 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** below).

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
Tell your doctor if you are taking, have recently taken or might take any other medicines.

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.

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Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 unborn child.

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
Certain side effects such as dizziness and sleepiness have been reported with Ertapenem, which may affect your ability to drive or operate machinery.
Do not drive or use any tools or machines **until you know how you react** to this medicine.

Ertapenem powder contains sodium
This medicine contains approximately 137 mg sodium (main component of cooking / table salt) in each 1.0 g dose. This is equivalent to 6.85 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Ertapenem

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

The recommended dose:
- Adults and adolescents aged 13 years and older: 1 gram (g) given once a day.
- Children aged 3 months to 12 years: 15 mg/kg given twice daily (not to exceed 1 g/day).

Your doctor will decide how many days' treatment you need. It is very important that you continue to receive Ertapenem for as long as your doctor prescribes it.

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

If you are given 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.

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.

Side effects in adults 18 years of age and older:

Common side effects (may affect up to 1 in 10 people):

- 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 blood platelet count
- Changes in liver function tests

Uncommon side effects (may affect up to 1 in 100 people):

- 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 tests and urine tests

Rare side effects (may affect up to 1 in 1,000 people):

- 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
- The skin may become hard at the site of injection
- Swelling of the skin blood vessels

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- 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.

If you experience raised or fluid-filled skin spots over a large area of your body, tell your doctor or nurse straight away.

Side effects in children and adolescents (3 months to 17 years of age):

Common side effects (may affect up to 1 in 10 people):
- Diarrhoea
- Nappy rash
- Pain at the infusion site
- Changes in white blood cell count
- Changes in liver function tests

Uncommon side effects (may affect up to 1 in 100 people):
- 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 of unknown frequency (frequency cannot be estimated from the available data):
- Hallucinations
- Altered mental status (including aggression)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ertapenem

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container.
The expiry date refers to the last day of that month.

Store below 25°C in the original package to protect from moisture.

After dilution: Chemical and physical in-use stability for diluted solutions (approximately 20 mg/ml ertapenem) has been demonstrated for 6 hours at 25°C or for 24 hours at 2 to 8°C (in a refrigerator). Solutions should be used within 4 hours of their removal from the refrigerator.
Do not freeze solutions of Ertapenem.

From a microbiological point of view, the product should be used immediately. If not use immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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

6. Contents of the pack and other information

What Ertapenem contains
The active substance is ertapenem 1 g (as ertapenem sodium).
The other ingredients are: sodium bicarbonate 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.

Ertapenem is supplied in packs of 1 vial or 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
ACS Dobfar S.p.A
Viale Addetta 4/12
20067 Tribiano (MI)
Italy

Manufacturer
ACS Dobfar S.p.A.
Nucleo Industriale S. Atto,
S. Nicolò a Tordino, 64100 Teramo, Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Netherlands: Ertapenem Added Pharma 1 g poeder voor concentraat voor oplossing voor infusie

France: ERTAPENEM ACS DOBFAR 1 g, poudre pour solution à diluer pour perfusion

Italy: Ertapenem ACS Dobfar

Romania: Ertapenem ACS Dobfar 1 g pulbere pentru concentrat pentru soluţie perfuzabilă

United Kingdom (Northern Ireland): Ertapenem 1 g powder for concentrate for solution for infusion

This leaflet was last revised in 04/2023

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

Instructions on how to reconstitute and dilute Ertapenem:

Powder	Reconstitution solvent	Volume to be added	Approx. displacement volume
1 g	Water for Injection	10 ml	0.7 ml
1 g	Sodium chloride 9 mg/ml (0.9 %) solution	10 ml	0.7 ml

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 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 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 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. Diluted solutions should be used immediately. If not used immediately, in use storage

times are the responsibility of the user. Diluted solutions (approximately 20 mg/ml ertapenem) are physically and chemically stable for 6 hours at room temperature (25°C) or for 24 hours at 2 to 8°C (in a refrigerator). Solutions should be used within 4 hours of their removal from the refrigerator.
Do not freeze the reconstituted solutions.

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.

The reconstituted solutions should be inspected visually for particulate matter and discolouration 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.