Package Leaflet: Information for the patient

Ertapenem CIPLA 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, or pharmacist or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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What is in this leaflet

1. What Ertapenem CIPLA is and what it is used for

Ertapenem CIPLA 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 CIPLA can be given to adults and children from 3 months of age and older.

This medicine is used for:

- Treatment:
  Your doctor has prescribed Ertapenem CIPLA because you or your child has one (or more) of the following types of infection:
  - Infection in the abdomen (stomach)
  - Infection affecting the lungs (pneumonia)
  - Gynaecological infections
  - Skin infections of the foot in diabetic patients.

- 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 CIPLA

Ertapenem CIPLA must not be given
- 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 or pharmacist or nurse before you are given Ertapenem CIPLA.

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.

It is important that you tell your doctor if you have diarrhoea before, during or after your treatment with Ertapenem CIPLA. 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 CIPLA' 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 (fits).

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.

Children and adolescents (3 months to 17 years of age)
Experience with Ertapenem CIPLA 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 with use of this medicine in children under 3 months of age.

Other medicines and Ertapenem CIPLA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, 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 CIPLA can affect the way some other medicines work. Your doctor will decide whether you should use Ertapenem CIPLA in combination with these medicines.

Pregnancy and breast-feeding
It is important that you tell your doctor if you are pregnant or are planning to become pregnant before receiving Ertapenem CIPLA.
Ertapenem CIPLA has not been studied in pregnant women. Ertapenem CIPLA 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 CIPLA.
Women who are receiving Ertapenem CIPLA should not breast-feed, because it has been found in human milk and the breast-fed baby may therefore be affected.

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

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

Ertapenem CIPLA contains sodium

This medicine contains 137 mg sodium (main component of cooking/table salt) per 1 g of Ertapenem for Injection. This is equivalent to 6.85% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ertapenem CIPLA is given

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

The recommended dose of Ertapenem CIPLA:

- For adults and adolescents 13 years of age and older: 1 gram (g) given once a day.
- For children 3 months to 12 years of age: 15 mg/kg given twice daily (not to exceed 1 g/day).
- For prevention of surgical site infections following surgery of the colon or rectum: 1 g administered as a single intravenous dose 1 hour before surgery.

Your doctor will decide the duration of your treatment.
It is very important that you continue receiving Ertapenem CIPLA for as long as your doctor prescribes it.

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

If you miss a dose of Ertapenem CIPLA
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 this medicine 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.**

Other side effects:

Common: 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 platelet count
- Changes in liver function tests

Uncommon: may affect up to 1 in 100 people
- Dizziness, sleepiness, sleeplessness, confusion, seizures
- 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

Rare: 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.

Not known: frequency cannot be estimated from the available data (reported since the medicine has been marketed)
- 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):

Common: 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: 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

Not known: frequency cannot be estimated from the available data (reported since the medicine has been marketed)
- 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 Yellow Card Scheme Website: 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 CIPLA

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 carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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 CIPLA contains
- The active ingredient is ertapenem 1 g.
- The other ingredients are: sodium bicarbonate (E500) and sodium hydroxide (E524).

What Ertapenem CIPLA looks like and contents of the pack
Ertapenem is a white to light yellow, 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 of the medicine.

Ertapenem CIPLA is supplied in a pack containing 10 vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
CIPLA (EU) Limited,
Dixcart House,
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The following information is intended for medical or healthcare professionals only:

Instructions of how to reconstitute and dilute Ertapenem CIPLA:

For single use only.

Preparation for intravenous administration:
Ertapenem CIPLA 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 CIPLA 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 CIPLA 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 CIPLA 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.
range 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.

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

Any antibiotic residual solution as well as all materials that have been used for administration should be disposed of in accordance with local requirements.