2D Matrix Code position may change as per Supplier's m/c requirement

Ertapenem 1 g
N17648

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Milpharm

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 ilness 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

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 are given Ertapenem

Do not use 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 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.

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 foetus.

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 137 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 6.85% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use 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.

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 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.

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.

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, 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

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

Not known : (frequency cannot be estimated from the available data):
- hallucinations
- decreased consciousness
- altered mental status (including aggression, delirium, disorientation, mental status changes)

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.

Instruction for inserting the needle into the rubber stopper:

In order to avoid a coring phenomenon of the plug, when inserting the needle into the rubber stopper, it is recommended to use a needle with a 21-gauge or smaller diameter needle for the reconstitution of the product.

Needle should be inserted only at the center of the rubber stopper, in vertical direction.

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.

Black

- 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.

Children and adolescents (3 months to 17 years of age):
Common (may affect up to 1 in 10 people):
- Diarrhoea
- Diaper 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):
- Hallucinations
- Altered mental status (including aggression)

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 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 and the vial after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

After reconstitution: reconstituted solutions should be used immediately.

After Dilution:
Chemical and physical in-use stability of diluted solutions has been demonstrated for 6 hours at 15-25 °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, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use this medicine if you notice (the presence of particles in the reconstituted solution or its incorrect coloring or signs of damage).

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 1 g.

Each vial contains 1.0 g ertapenem.

The other ingredients are: Sodium Hydrogen carbonate, sodium hydroxide to adjust pH to 7.6 and sodium hydroxide used as Buffering agent.

What Ertapenem looks like and contents of the pack
Ertapenem is white to off-white 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.

20ml Type-I glass vials with grey bromo butyl rubber stopper and sealed with aluminum seal having polypropylene disc**.**

Ertapenem is supplied in packs of 1 vial, 5 vials and 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer
APL Swift Services (Malta) Ltd,
HF26, Hal Far Industrial EstateHal Far,
Birzebbugia, BBG 3000, Malta.

or

Milpharm Limited.
Ares Block, Odyssey Business Park,
West End Road, Ruislip HA4 6QD,
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or

Generis Farmacêutica, S.A.,
Rua João de Deus, 19, 2700-487 Amadora,
Portugal

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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

After reconstitution:
reconstituted solutions should be used immediately.

After Dilution:
Chemical and physical in-use stability of diluted solutions has been demonstrated for 6 hours at controlled room temperature 15-25 °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, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions 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 medicinal product or waste material should be disposed of in accordance with local requirements.

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