PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ERTAVA™

1 g sterile powder for solution for injection or infusion

Ertapenem

Sugar free

Read all of this leaflet carefully before you are given ERTAVA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What ERTAVA is and what it is used for

ERTAVA contains ertapenem, which is an antibiotic of the beta-lactam group.

Ertapenem can kill a wide range of bacteria (germs) that cause infections in various parts of the body.

ERTAVA may be given to persons 3 months of age and older.

Your doctor may have prescribed ERTAVA to you or your child if you have one (or more) of the following types of infection:

- Infection in the abdomen
- Skin infections, including diabetic foot infections
- Infection in the lungs (pneumonia)
- Certain urinary infections
- Acute pelvic infections

2. What you need to know before you use ERTAVA

ERTAVA should not be administered to you:

- if you are hypersensitive (allergic) to the active substance (ertapenem) or any of the other ingredients of ERTAVA (listed in section 6);
- if you are allergic to other beta-lactam antibiotics such as penicillins, cephalosporins (used to treat various infections);
- if you have bacterial meningitis (infection and inflammation of the membranes and fluid around the brain and spinal cord);
- if you are allergic to lidocaine (lignocaine) hydrochloride (a local anaesthetic). If ERTAVA is injected into the muscle, it is dissolved in a lidocaine (lignocaine) injection.

Warnings and precautions

Tell your doctor or healthcare provider before ERTAVA injection is given if you:

- have allergies to other medicines or other substances;
- get an allergic reaction (such as swelling of the face, tongue or throat, trouble breathing or swallowing, skin rash) during treatment (tell your doctor

straight away as you may need urgent medical treatment). Serious, sometimes fatal allergic reactions have been reported with ertapenem (contained in ERTAVA). See section 4;

- have central nervous system disorders, such as localised tremors (shaking), or seizures ("fits");
- are taking medicines called valproic acid or divalproex sodium (see "Other medicines and ERTAVA" below);
- have advanced kidney disease and if you get dialysis treatment;
- are going to have an operation that may take longer than 4 hours.

It is important that you tell your doctor if you have diarrhoea before, during or after your treatment with ERTAVA. 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.

Ertapenem may sometimes cause brain problems like confusion, seizures, or changes in consciousness (encephalopathy). If you notice these symptoms, your doctor might stop ERTAVA. People with kidney issues are more likely to experience these problems, and it might take longer for them to get better.

ERTAVA kills certain bacteria, but other bacteria and fungi may continue to grow more than normal and cause thrush or diarrhoea. This is called overgrowth. Your doctor will monitor you for overgrowth and treat you if necessary. See section 4 "*Possible side effects*".

Children

Experience with ERTAVA 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. ERTAVA is therefore contraindicated in this age group (see “ERTAVA should not be administered”).

Other medicines and ERTAVA

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Tell your doctor if you take:

- valproic acid or divalproex sodium (medicines used to treat epilepsy, bipolar disorder, migraines, or schizophrenia).

This is because ERTAVA can affect the way some other medicines work. Your doctor will decide whether you should use ERTAVA in combination with other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving ERTAVA.

Safety in pregnancy has not been established.

ERTAVA is passed into in human breastmilk. Safety in nursing mothers has not been established. If you receive ERTAVA you should not breastfeed your baby as the baby may be affected.

There is no information on the effect of ERTAVA on fertility in men and women.

Driving and using machines

Dizziness and sleepiness may be side effects of ERTAVA, which may affect your ability to do tasks or activities requiring mental alertness such as driving, riding, flying, sailing, operating machines/equipment.

It is not always possible to predict to what extent ERTAVA may interfere with the daily activities of a patient. You should ensure that you do not engage in above activities until you are aware of the measure to which ERTAVA affects them.

ERTAVA contains sodium

ERTAVA contains 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 ERTAVA

Do not share medicine prescribed for you with any other person.

You will not be expected to give yourself ERTAVA. It will be given to you by a person who is qualified to do so.

Your healthcare provider will prepare ERTAVA and give it to you intravenously (into a vein) or intramuscularly (into a muscle).

The recommended dose of ERTAVA 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 however prescribe a dose just suitable for you, or your child. The dose will depend on the type of infection you have and the condition of your kidneys.

Your doctor will decide for how long to treat you, or your child. The duration will depend on the type of infection and your response on the treatment.

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

If you are given more ERTAVA than you should

Since a healthcare provider will administer ERTAVA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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

If you miss a dose of ERTAVA

Since a healthcare provider will administer ERTAVA, it is unlikely that the dose will be missed.

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

4. Possible side effects

ERTAVA can have side effects.

Not all side effects reported for ERTAVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ERTAVA, please consult your healthcare provider for advice.

If any of the following happens, stop using ERTAVA and tell your doctor immediately:

- Serious allergic reactions: wheezing, difficulty breathing, swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- "DRESS" (drug rash with eosinophilia and systemic symptoms): This is a serious or life-threatening allergic reaction that may affect your skin or other parts of your body, such as your liver or blood cells. You may have fever, tender swollen glands in the neck, armpits and groin and a rash.
- Serious skin disorders, such as blistering or peeling of the skin, lesions on the skin and mucous membranes, an acute medicine rash (numerous small fluid-filled skin spots within large areas of red swollen skin).
- Severely upset stomach (pseudomembranous colitis). You may have inflammation of the bowels, that could be life-threatening. The symptoms may include severe abdominal pain and diarrhoea, or diarrhoea tinged with blood, vomiting and fever.

These are all very serious side effects. If you have them, you may have had a serious reaction to ERTAVA. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Adults 18 years of age and older:

Frequent side effects:

- Headache
- Problems with the vein into which the medicine is given (including inflammation, formation of a lump, swelling at the injection site)

- Diarrhoea, nausea, vomiting
- Rash, itching, skin redness (erythema)
- Increase in various liver enzymes. Some of the signs may be yellowing of the skin, whites of the eyes, pain or swelling in the abdomen, nausea and vomiting, dark urine, pale-coloured stools
- Increased blood platelet count. Some of the signs may be headache, numbness of hands or feet, weakness, bleeding in mouth or gums, bloody stool, easy bleeding or bruising, nosebleeds.

Less frequent side effects:

- Yellowing of the eyes and skin (jaundice or a liver disorder)
- Infections, such as vaginal thrush, yeast and fungal infections, wound infection after an operation, urinary tract infection
- Laboratory tests may show very low white cell or blood platelet counts (which may lead to more infections or bleeding)
- Anorexia (eating disorder)
- Low blood sugar
- Sleepiness, sleeplessness
- Anxiety
- Depression
- Confusion
- Seizure, tremor
- Dizziness
- Altered taste sensation
- Fainting

- Changes to the white part of the eye
- Slow heart rate, irregular heartbeat, quick heartbeat
- Low or high blood pressure
- Bleeding
- Shortness of breath
- Sore throat, nasal congestion
- Cough, abnormal breathing sounds, wheezing
- Nose bleeds
- Constipation
- Oral thrush
- Abdominal pain, inflammation of the membrane that lines the abdomen in the pelvic area
- Acid regurgitation, indigestion
- Dry mouth
- Difficulty swallowing
- Faecal incontinence
- Inflammation of the liver and/or the gallbladder
- Skin inflammation
- Muscle cramp, shoulder pain
- Kidney function affected. Problems to urinate or to pass adequate urine (acute renal insufficiency)
- Abortion
- Genital bleeding

- Fatigue
- Leaking of fluid into the tissue and skin around the injection site
- Fever, feeling unwell
- Swelling
- Chest pain
- Changes in various laboratory blood and urine tests, indicating for example effects on the liver, kidneys, sugar, blood chemistry, cholesterol.

Unknown frequency:

- Hallucinations (hearing and seeing things that do not exist)
- Altered mental state (including aggression, disturbance of mental abilities, disorientation)
- Decreased level of consciousness
- Uncontrolled, involuntary movement, change in walking pattern, spasmodic, jerky contractions
- Encephalopathy (brain problems) (see “Warnings and Precautions”)
- Unsteady walking
- Stained teeth
- Weak muscles.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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

Frequent side effects:

- Diarrhoea, vomiting

- Nappy rash, rash
- Pain at the infusion site, phlebitis (inflammation or swelling where the infusion was given)
- Changes in white blood cell count, changes in liver function tests.

Less frequent side effects:

- Headache
- Hot flush, high blood pressure
- Discoloured faeces, black tar-like faeces
- Skin redness, skin rash, tiny purple, red, or brown spots on the skin
- Burning, itching, redness and warmth at infusion site, redness at injection site
- Increase in platelet count and changes in other blood clotting tests.

Frequency unknown:

- Hallucinations
- Encephalopathy (brain problems) (see “Warnings and Precautions”)
- Decreased level of consciousness
- Uncontrolled, involuntary movement, change in walking pattern, spasmodic, jerky contractions, tremor (shakiness)
- Altered mental status (including feeling aggressive, restless, confused, or disoriented)
- Teeth staining
- Muscular weakness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ERTAVA.

5. How to store ERTAVA

Store all medicines out of the reach of children.

ERTAVA will be stored in the pharmacy or in the hospital wards.

Vial with powder:

Store at or below 25 ºC. Do not freeze.

Do not use ERTAVA after the expiry date which is stated on the vial and carton. The expiry date refers to the last day of that month.

After reconstitution:

For single use only.

After dilution: Chemical and physical in-use stability for diluted solutions has been demonstrated for 6 hours at or below 25 °C and 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 ERTAVA.

Do not use ERTAVA if you notice particulate matter and discolouration in the reconstituted solutions.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ERTAVA contains

- The active substance is Ertapenem 1 g.
- The other ingredients are sodium hydrogen carbonate and sodium hydroxide.

What ERTAVA looks like and contents of the pack

ERTAVA is a sterile white or almost white powder for solution for injection or infusion.

Solutions of ERTAVA range from colourless to pale yellow and is free from visible particles.

ERTAVA is supplied in 20 mL colourless clear Type I glass vials with chlorobutyl rubber stoppers and 20 mm aluminium-plastic cap.

Supplied in packs of 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Abex Pharmaceutica (Pty) Ltd.

Suite C, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park

0181

Tel: +27 (0)12 997 6974

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