APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

INVABEX 1 g sterile powder for solution for injection or infusion

Ertapenem

Sugar free

Read all of this leaflet carefully before you are given INVABEX

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

What is in this leaflet

1. What INVABEX is and what it is used for

INVABEX 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.

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

Your doctor may have prescribed INVABEX 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 are administered INVABEX

INVABEX should not be administered:

- if you are hypersensitive (allergic) to the active substance (ertapenem) or any of the other ingredients of INVABEX (see 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 INVABEX is injected into the muscle, it is dissolved in lidocaine (lignocaine) injection.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

- if you have allergies to other medicines (including other antibiotics) or other substances
- if you 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 INVABEX). See section 4
- if you have central nervous system disorders, such as localised tremors (shaking), or seizures (fits)
- if you are taking medicines called valproic acid or divalproex sodium (see Other medicines and INVABEX below)
- if you have advanced kidney disease and if you get dialysis treatment
- if you 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 INVABEX. 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.

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

There is no experience in children under 3 months of age.

Experience with INVABEX is limited in children less than two years of age.

Other medicines and INVABEX

Always tell your healthcare provider if you are taking any other medicine. (This includes 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)
- probenecid (a medicine for gout).

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 INVABEX.

Safety in pregnancy has not been established.

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

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

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Dizziness and sleepiness may be side effects of INVABEX. If you have these side effects, you should not drive or handle tools or machinery.

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

INVABEX contains sodium

INVABEX contains approximately 6,0 millimoles (approximately 137 mg) of sodium per 1,0 g dose. Tell your doctor if you are on a salt restricted diet.

3. How to use INVABEX

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

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

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

Adults and adolescents 13 years of age and older:

The recommended dose of INVABEX for adults and adolescents 13 years of age and older is 1 gram (g) given once a day.

Children 3 months to 12 years:

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 INVABEX for as long as your doctor prescribes it.

If you have the impression that the effect of INVABEX is too strong or too weak, tell your doctor or pharmacist.

If you are administered more INVABEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you forget to use INVABEX

Since a healthcare professional will administer INVABEX, it is unlikely that the dose will be missed.

4. Possible side effects

INVABEX can have side effects.

Not all side effects reported for INVABEX are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using INVABEX, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using INVABEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- fainting
- 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, Stevens-Johnson syndrome (a complex allergic reaction, with skin and mucous membrane lesions, which may become severe and may be fatal)

- 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 allergic reaction to INVABEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Adults 18 years of age and older:

- yellowing of the eyes and skin (jaundice or a liver disorder)
- seizure, tremor
- slow heart rate, irregular heartbeat, quick heartbeat
- low or high blood pressure
- an allergic reaction called Kounis syndrome (you may experience symptoms such as chest discomfort, acute chest pain, faintness, headache, nausea and dyspnoea)
- kidney function affected. Problems to urinate or to pass adequate urine (acute renal insufficiency)
- hallucinations (hearing and seeing things that do not exist)
- altered mental state (including aggression, disturbance of mental abilities, disorientation, confusion, memory loss, personality changes)
- decreased level of consciousness.

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

- hallucinations
- altered mental status (including aggression)
- high blood pressure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

Adults 18 years of age and older:

- 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
- 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
- muscle cramp, shoulder pain.

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

- diarrhoea, vomiting

- nappy rash, rash
- pain at the infusion site
- changes in white blood cell count, changes in liver function tests.

Less frequent side effects:

Adults 18 years of age and older:

- infections, such as oral thrush, 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
- altered taste sensation
- changes to the white part of the eye
- bleeding
- shortness of breath, Sore throat, nasal congestion, Cough, abnormal breathing sounds, wheezing
- nose bleeds
- constipation
- 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 redness, inflammation
- skin blisters in a clustered arrangement on the face and possibly perineum, that may spread to the limbs, trunk, hands, feet and scalp (linear IgA bullous disease)
- miscarriage, 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.

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

- headache
- hot flush
- 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.

The following side effects have been reported but the frequency for them to occur is not known:

Adults 18 years of age and older:

- uncontrolled, involuntary movement, spasmodic, jerky contractions
- unsteady walking
- stained teeth
- weak muscles.

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 INVABEX. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store INVABEX

Store all medicines out of reach of children.

Vial with powder:

Store at or below 25 ºC. Do not freeze.

Do not use INVABEX 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.

Reconstituted solutions

From a microbial point of view, the product should be used immediately.

Reconstituted intramuscular injection solution:

The reconstituted IM solution should be used within 1 hour after preparation.

Reconstituted intravenous infusion solution:

If not used immediately, the storage time 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/dilution has taken place in controlled and validated aseptic conditions.

Diluted solutions (approximately 20 mg/mL ertapenem) are physically and chemically stable 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 INVABEX.

Do not use INVABEX 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 INVABEX contains

The active substance is ertapenem 1 g.

The other ingredients are sodium hydrogen carbonate and sodium hydroxide for pH adjustment.

What INVABEX looks like and contents of the pack

INVABEX is a sterile white to yellowish powder for solution for injection or infusion. Solutions of INVABEX range from colourless to pale yellow and is free from visible particles.

INVABEX is supplied in 20 ml colourless clear Type I glass vials with chlorobutyl stoppers and aluminium flip-off overseals.
Supplied in packs of 1 or 10 vials.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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