PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

INVEXEM™
1 g sterile powder for solution for injection or infusion
Ertapenem
Sugar free

Read all of this leaflet carefully before you are given INVEXEM

- 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 INVEXEM is and what it is used for
2. What you need to know before you use INVEXEM
3. How to use INVEXEM
4. Possible side effects
5. How to store INVEXEM
6. Contents of the pack and other information

1. What INVEXEM is and what it is used for

INVEXEM 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.
INVEXEM may be given to persons 3 months of age and older.
Your doctor may have prescribed INVEXEM 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 INVEXEM

INVEXEM should not be administered to you:

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

Warnings and precautions
Tell your doctor or healthcare provider before INVEXEM 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 INVEXEM). 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 INVEXEM" 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 INVEXEM. 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 INVEXEM. People with kidney issues are more likely to experience these problems, and it might take longer for them to get better.

INVEXEM 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 INVEXEM 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. INVEXEM is therefore contraindicated in this age group (see "INVEXEM should not be administered").

Other medicines and INVEXEM
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 INVEXEM can affect the way some other medicines work. Your doctor will decide whether you should use INVEXEM 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 INVEXEM.

Safety in pregnancy has not been established.

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

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

Driving and using machines
Dizziness and sleepiness may be side effects of INVEXEM, 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 INVEXEM 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 INVEXEM affects them.

INVEXEM contains sodium
INVEXEM 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 INVEXEM

Do not share medicine prescribed for you with any other person.
You will not be expected to give yourself INVEXEM. It will be given to you by a person who is qualified to do so.
Your healthcare provider will prepare INVEXEM and give it to you intravenously (into a vein) or intramuscularly (into a muscle).
The recommended dose of INVEXEM 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 INVEXEM for as long as your doctor prescribes it.

If you are given more INVEXEM than you should
Since a healthcare provider will administer INVEXEM, 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 INVEXEM, contact your doctor or another healthcare provider immediately.

If you miss a dose of INVEXEM
Since a healthcare provider will administer INVEXEM, 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

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

If any of the following happens, stop using INVEXEM 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 INVEXEM. 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 INVEXEM.

5. How to store INVEXEM

Store all medicines out of the reach of children.
INVEXEM will be stored in the pharmacy or in the hospital wards.
Vial with powder:
Store at or below 25 °C. Do not freeze.
Do not use INVEXEM 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 INVEXEM.
Do not use INVEXEM 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 INVEXEM contains

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

What INVEXEM looks like and contents of the pack
INVEXEM is a sterile white or almost white powder for solution for injection or infusion.
Solutions of INVEXEM range from colourless to pale yellow and is free from visible particles.
INVEXEM 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

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd
Suite A, Rubenstein Ridge
617 Rubenstein Drive
Moreleta Park, 0181

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

INVEXEM™
1 g steriele poeier vir oplossing vir inspuiting of infusie
Ertapenem
Suikervry

Lees die hele inligtingsblad aandagtig deur voordat INVEXEM aan jou gegee word

- Hou hierdie inligtingsblad. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad
1. Wat is INVEXEM en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy INVEXEM gebruik
3. Hoe om INVEXEM te gebruik
4. Moontlike newe-effekte
5. Hoe om INVEXEM te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is INVEXEM en waarvoor word dit gebruik

INVEXEM bevat ertapenem, wat 'n antibiotikum van die beta-laktaamgroep is.
Ertapenem kan 'n wye verskeidenheid bakterieë (kieme) wat infeksies in verskillende dele van die liggaam veroorsaak, doodmaak.
INVEXEM kan aan persone van 3 maande en ouer gegee word.
Jou dokter kan moontlik INVEXEM aan jou of jou kind voorskryf indien jy/hy/sy een (of meer) van die volgende soorte infeksies het:

- Infeksie in die buik
- Velinfeksies, insluitend diabetiese voetinfeksies
- Infeksie in die longe (pneumonie)
- Sekere urinêre infeksies
- Akute bekkeninfeksies

2. Wat jy moet weet voordat jy INVEXEM gebruik

INVEXEM moet nie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir die aktiewe bestanddeel (ertapenem) of enige van die ander bestanddele van INVEXEM (gelys in afdeling 6);
- indien jy allergies is vir ander beta-laktaamantibiotika, soos penisilliene, kefalosporiene (gebruik vir die behandeling van verskeie infeksies);
- indien jy bakteriële meningitis het (infeksie en ontsteking van die vliese en vloeistof rondom die brein en rugmurg);
- indien jy allergies is vir lidokaïen (lignokaïen) hidrochloried ('n plaaslike verdowingsmiddel). Indien INVEXEM in die spier ingespuit word, word dit in 'n lidokaïen (lignokaïen)-inspuiting opgelos.

Waarskuwings en voorsorgmaatreëls
Voordat INVEXEM-inspuiting aan jou gegee word, lig jou dokter of gesondheidsorgverskaffer in as jy:

- allergieë het vir ander medisyne of ander stowwe;
- 'n allergiese reaksie (soos swelling in die gesig, tong of keel, asemhalings- of slukprobleme, veluitslag) tydens die behandeling kry (lig dadelik jou dokter in, aangesien jy dringende mediese behandeling kan benodig). Ernstige, soms noodlottige allergiese reaksies is met ertapenem (bevat in INVEXEM) aangemeld. Sien afdeling 4;
- versteurings in die sentrale senuweestelsel, soos gelokaliseerde bewing (bewerigheid) het, of aanvalle (stuipe) kry;
- medisyne genaamd valproïensuur of natriumdivalproeks neem (sien "Ander medisyne en INVEXEM" hieronder);
- gevorderde niersiekte het en dialise behandeling ondergaan;
- 'n operasie gaan ondergaan wat dalk meer as 4 uur kan duur.

Dit is belangrik dat jy dit vir jou dokter sê as jy diarree kry voor, tydens of na jou behandeling met INVEXEM. Dit is omdat jy 'n toestand kan hê wat bekend staan as kolitis ('n ontsteking van die dikderm). Moenie enige medisyne neem om die diarree te behandel sonder om dit eers met jou dokter te bevestig nie.
Ertapenem kan soms breinprobleme soos verwarring, aanvalle of veranderinge in bewussyn (ensefalopatie) veroorsaak. Indien jy hierdie simptome opmerk kan jou dokter INVEXEM staak. Mense met nierprobleme is meer geneig om hierdie probleme te ervaar en dit kan langer neem vir hulle om beter te word.
INVEXEM maak sekere bakterieë dood, maar ander bakterieë en swamme kan meer as gewoonlik aanhou groei en sproei of diarree veroorsaak. Dit staan bekend as oorgroeiing. Jou dokter sal jou monitor vir oorgroeiing en jou behandel indien nodig. Sien afdeling 4 "*Moontlike newe-effekte*".

Kinders
Ervaring met INVEXEM by kinders onder twee jaar is beperk. In hierdie ouderdomsgroep sal jou dokter besluit oor die potensiële voordeel van die gebruik daarvan.
Daar is geen ondervinding met kinders onder 3 maande nie. INVEXEM is dus teenaangedui in hierdie ouderdomsgroep (sien "INVEXEM moet nie aan jou toegedien word nie").

Ander medisyne en INVEXEM
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. Dit sluit alle komplementêre of tradisionele medisyne in.
Lig jou dokter in indien jy die volgende neem:

- valproïensuur of natriumdivalproeks (medisyne wat gebruik word vir die behandeling van epilepsie, bipolêre versteuring, migraine of skisofrenie).

Dit is omdat INVEXEM die manier waarop ander medisyne werk, kan beïnvloed. Jou dokter sal besluit of jy INVEXEM in kombinasie met hierdie medisyne kan gebruik.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy INVEXEM ontvang.

Die veiligheid tydens swangerskap is nie vasgestel nie.

INVEXEM kom in borsmelk voor. Veiligheid in moeders wat borsvoed is nie vasgestel nie. Indien jy INVEXEM ontvang, moet jy nie jou baba borsvoed nie, aangesien dit die baba kan beïnvloed.

Daar is geen inligting oor die effek van INVEXEM op vrugbaarheid by mans en vroue nie.

Bestuur en die gebruik van masjinerie
Duiseligheid en lomerigheid kan newe-effekte van INVEXEM wees en kan jou vermoë belemmer om take of aktiwiteite uit te voer wat verstandelike wakkerheid vereis, soos om te bestuur, perd te ry, te vlieg, te seil of masjinerie/toerusting te gebruik.
Dit is nie altyd moontlik om te voorspel tot hoe 'n mate INVEXEM die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie.
Jy moet seker maak dat jy nie aan enige van die bogenoemde aktiwiteite deelneem totdat jy weet in watter mate INVEXEM jou beïnvloed nie.

INVEXEM bevat natrium
INVEXEM bevat 137 mg natrium (hoofkomponent van kook-/tafelsout) in elke 1,0 g dosis. Dit is gelykstaande aan 6,85 % van die aanbevole maksimum daaglikse hoeveelheid natrium in die voeding vir 'n volwassene.

3. Hoe om INVEXEM te gebruik

Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Daar sal nie van jou verwag word om INVEXEM aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.
Jou gesondheidsorgverskaffer sal INVEXEM voorberei en dit intraveneus (in 'n aar) of intramuskulêr (in 'n spier) aan jou toedien.
Die aanbevole dosis van INVEXEM vir volwassenes en adolessente 13 jaar en ouer is 1 gram (g), een keer per dag toegedien.
Die aanbevole dosis vir kinders van 3 maande tot 12 jaar oud is 15 mg/kg, wat twee keer per dag gegee word (nie meer as 1 g/dag nie).
Jou dokter sal egter 'n dosis voorskryf wat geskik is vir jou of jou kind. Die dosis sal afhang van die tipe infeksie wat jy het en die toestand van jou niere.
Jou dokter sal besluit hoe lank jy of jou kind behandel moet word. Die duur sal afhang van die tipe infeksie en jou reaksie op die behandeling.
Dit is baie belangrik dat jy aanhou om INVEXEM te ontvang vir solank as wat jou dokter dit voorskryf.

Indien jy meer INVEXEM ontvang as wat jy moes
Aangesien 'n gesondheidsorgverskaffer INVEXEM sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.
Indien jy bekommerd is dat jy miskien te veel INVEXEM ontvang het, kontak dadelik jou dokter of ander gesondheidsorgverskaffer.

Indien jy 'n dosis INVEXEM oorgeslaan het
Aangesien 'n gesondheidsorgverskaffer INVEXEM sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.
Indien jy bekommerd is dat jy 'n dosis oorgeslaan het, kontak dadelik jou dokter of 'n ander gesondheidsorgverskaffer.

4. Moontlike newe-effekte

INVEXEM kan newe-effekte hê.
Nie alle newe-effekte wat vir INVEXEM aangemeld is, word in hierdie inligtingsblad genoem nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy INVEXEM ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om INVEXEM te gebruik en lig dadelik jou dokter in:

- Ernstige allergiese reaksies: hyging, moeilike asemhaling, swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- 'DRESS' ('n medisyne-uitslag met eosinofilie en sistemiese simptome): Dit is 'n ernstige of lewensgevaarlike allergiese reaksie wat jou vel of ander dele van jou liggaam, soos jou lewer of bloedselle, kan aantas. Jy kan koors, gevoelige geswelde kliere in die nek, oksels en lies, en 'n uitslag hê.
- Ernstige veltoestande soos blase of afskilfering van die vel, letsels van die vel en slymvliese, akute geneesmiddeluitslag (talle klein, vloeistofgevulde velkolle binne groot areas van rooi, geswolle vel).
- Erg omgekrapte maag (pseudomembraneuse kolitis). Jy kan ontsteking van die dermkanaal hê, wat lewensbedreigend kan wees. Die simptome kan erge buikpyn en diarree, of diarree met bloed, braking en koors insluit.

Hierdie newe-effekte is almal baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op INVEXEM hê. Jy kan dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende waarneem:

Volwassenes 18 jaar en ouer:
Gereelde newe-effekte:

- Hoofpyn
- Probleme met die aar waarin die medisyne gegee word (insluitend ontsteking, vorming van 'n knop, swelling by die inspuitplek)
- Diarree, naarheid, braking
- Uitslag, jeuk, velrooiheid (eriteem)
- Toename in verskeie lewerensieme. Sommige van die tekens kan wees dat die vel en oogwitte geel verkleur, pyn of swelling in die buik, naarheid en braking, donker uriene, ligkleurige ontlasting
- Verhoogde bloedplaatjietelling. Sommige van die tekens kan wees hoofpyn, gevoelloosheid van hande of voete, swakheid, bloeding in die mond of tandvleis, bloederige stoelgang, maklike bloeding of kneusing, neusbloeding.

Minder gereelde newe-effekte:

- Geel verkleuring van die oë en vel (geelsug of 'n leweraandoening)
- Infeksies, soos vaginale sproei, gis- en swaminfeksies, wondinfeksie na 'n operasie, urienweginfeksie
- Laboratoriumtoetse kan 'n baie lae aantal witbloedselle of bloedplaatjies toon (wat tot meer infeksies of bloeding kan lei)
- Anoreksie (eetversteuring)
- Lae bloedsuiker
- Slaperigheid, slapeloosheid
- Angs
- Depressie
- Verwarring
- Aanvalle, bewing
- Duiseligheid
- Verandering in smaaksensasie
- Floute
- Verandering in die wit deel van die oog
- Stadige hartklop, ongereelde hartklop, vinnige hartklop
- Lae of hoë bloeddruk
- Bloeding
- Kortasemigheid
- Seer keel, verstopte neus
- Hoes, abnormale asemgeluide, hyging
- Neusbloedings
- Hardlywigheid
- Sproei in die mond
- Buikpyn, ontsteking van die membraan wat die buik in die bekkenarea uitvoer
- Suurrefluks, slegte spysvertering
- Droë mond
- Sluk moeilik
- Fekale inkontinensie
- Inflammasie van die lewer en/of die galblaas
- Velontsteking
- Spierkrampe, skouerpyn
- Nierfunksie aangetas. Probleme om te urineer of voldoende uriene te vorm (akute verswakte nierfunksie)
- Aborsie
- Genitale bloeding
- Moegheid
- Lek van vloeistof in die weefsel en vel rondom die inspuitplek
- Koors, voel ongesteld
- Swelling
- Borspyn
- Veranderinge in verskeie bloed- en urientoetse in laboratoriums, wat byvoorbeeld effekte op die lewer, niere, suiker, bloedchemie en cholesterol aandui.

Frekwensie onbekend:

- Hallusinasies (hoor en sien dinge wat nie bestaan nie)
- Veranderde geestestoestand (insluitend aggressie, versteuring van verstandelike vermoëns, disoriëntasie)
- Verminderde vlak van bewussyn
- Ongekontroleerde, onwillekeurige bewegings, veranderinge in loopstyl, spasmodiese, rukkerige sametrekkings
- Ensefalopatie (breinprobleme) (sien "Waarskuwings en voorsorgmaatreëls")
- Wankelrige loopstyl
- Gevlekte tande
- Swak spiere.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Kinders en adolessente (3 maande tot 17 jaar oud):
Gereelde newe-effekte:

- Diarree, braking
- Luieruitslag, uitslag
- Pyn by die infusieplek, flebitis (inflammasie of swelling waar die infusie toegedien is)
- Veranderinge in witbloedseltellings, veranderinge in lewerfunksiewaardes.

Minder gereelde newe-effekte:

- Hoofpyn
- Warm gloede, hoë bloeddruk
- Verkleurde feses, swart teeragtige feses
- Rooi vel, veluitslag, klein pers, rooi, of bruin kolletjies op die vel
- Branderigheid, jeuk, rooiheid en warmte by infusieplek, rooiheid by die inspuitplek
- Verhoogde plaatjietelling en veranderinge in ander bloedstollingstoetse.

Frekwensie onbekend:

- Hallusinasies
- Ensefalopatie (breinprobleme) (sien "Waarskuwings en voorsorgmaatreëls")
- Verminderde vlak van bewussyn
- Ongekontroleerde, onwillekeurige bewegings, veranderinge in loopstyl, spasmodiese, rukkerige sametrekkings, tremor (bewerigheid)
- Veranderde geestestoestand (insluitend aggressie, rusteloosheid, verwardheid of disoriëntasie)
- Tande verkleur
- Spierswakheid

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf.
Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van INVEXEM te verskaf.

5. Hoe om INVEXEM te bewaar

Bewaar alle medisynes buite bereik van kinders.
INVEXEM sal in die apteek of hospitaalsaal bewaar word.
Flessie met poeier:
Bewaar by of benede 25 °C. Moenie vries nie.
Moenie na die vervaldatum wat op die flessie en kartonpakkie verskyn gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Na hersamestelling:
Slegs vir eenmalige gebruik.
Na verdunning: Chemiese en fisiese stabiliteit van verdunde oplossings tydens gebruik is aangetoon vir 6 uur by of benede 25 °C en vir 24 uur by 2 tot 8 °C (in 'n yskas). Oplossings moet binne vier uur nadat dit uit die yskas gehaal is, gebruik word.
Moenie oplossings van INVEXEM vries nie.
Moenie INVEXEM gebruik as jy deeltjies en verkleuring in die hersaamgestelde oplossings opmerk nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat INVEXEM bevat

- Die aktiewe bestanddeel is Ertapenem 1 g.
- Die ander bestanddele is natriumbikarbonaat en natriumhidroksied.

Hoe INVEXEM lyk en inhoud van die pakkie
INVEXEM is 'n steriele wit of byna wit poeier vir oplossing vir inspuiting of infusie.
Oplossings van INVEXEM kan wissel van kleurloos tot liggeel en is sonder sigbare deeltjies.
INVEXEM word verskaf in 20 mL kleurlose deursigtige tipe I glasflessies met chloorbutielrubberproppe en 20 mm aluminium-plastiekdoppe.
Verskaf in pakke van 1 of 10 flessies.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
Abex Pharmaceutica (Edms) Bpk.
Suite C, Rubenstein Ridge
Rubensteinrylaan 617
Moreleta Park, 0181
Tel: +27 (0)12 997 6974

Bemark deur:
AFT Pharmaceuticals SA (Edms) Bpk
Suite A, Rubenstein Ridge
617 Rubenstein Rylaan
Moreleta Park, 0181

Hierdie inligtingsblad is voorheen hersien
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Registrasienommer
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