

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****NIVAZEN 1 g powder for concentrate for solution for infusion****Ertapenem****Sugar free****Read all of this leaflet carefully before you are given NIVAZEN**

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

What is in this leaflet

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

1. What NIVAZEN is and what it is used for

NIVAZEN contains ertapenem which is an antibiotic of the beta-lactam group. It is used to kill a wide range of bacteria (germs) that cause infections in various parts of the body.

NIVAZEN can be given to patients 3 months of age and older.

Your doctor has prescribed NIVAZEN because you or your child has one (or more) of the following types of infection:

- Infection in the abdomen.
- Skin infections, including infections of the foot in diabetic patients.
- Infection affecting the lungs (pneumonia).
- Infections of the urinary tract.
- Acute infections of the pelvis.

2. What you need to know before you use NIVAZEN

NIVAZEN should not be administered to you:

- If you are hypersensitive (allergic) to ertapenem or any of the other ingredients of NIVAZEN (listed in section 6).
- If you are allergic to antibiotics such as penicillins, cephalosporins or carbapenems (which are used to treat various infections).
- If NIVAZEN will be administered into a muscle and you are allergic to local anaesthetics of the amide type, particularly lidocaine hydrochloride (medicines used to numb a part of your body).
- If you or your child have bacterial meningitis (infection and inflammation of the membranes and cerebrospinal fluid surrounding the brain and spinal cord).
- If your baby is younger than 3 months.

Warnings and precautions

Tell your doctor or health care provider before being given the injection,

Special care should be taken:

- If you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash) during treatment. Tell your doctor straight away as you may need urgent medical treatment.

- While antibiotics including NIVAZEN 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.
- If you have diarrhoea before, during or after your treatment with NIVAZEN. 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.
- If you are taking medicines called valproic acid or sodium valproate (see **Other medicines and NIVAZEN** below).
- If you have or have had any medical condition 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

Experience with NIVAZEN is limited in children less than two years of age. There is no experience in the treatment of NIVAZEN in children under 3 months of age.

Other medicines and NIVAZEN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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). Your doctor will decide whether you should use NIVAZEN in combination with these medicines.

Pregnancy and breastfeeding

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 health care provider for advice before NIVAZEN is given to you.

Pregnancy

NIVAZEN should not be used during pregnancy.

Breastfeeding

Ertapenem is passed into breast milk. Because of the potential for adverse reactions on the infant, you should not breastfeed your infant while receiving NIVAZEN.

Driving and using machines

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

NIVAZEN contains sodium

NIVAZEN contains approximately 6,0 mEq (approximately 137 mg) of sodium per 1,0 g dose which should be taken into consideration if you or your child is on a controlled sodium diet.

3. How to use NIVAZEN

NIVAZEN will always be prepared and given to you intravenously (into a vein) or intramuscularly (into a muscle) by a doctor or another health care professional. When administered intravenously, NIVAZEN should be infused over a period of 30 minutes.

The usual dose 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. It is very important that you continue to receive NIVAZEN for as long as your doctor prescribes it.

If you are given more NIVAZEN than you should receive

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

If you missed a dose of NIVAZEN

Since a health care provider will administer NIVAZEN, it is unlikely that the dose will be missed.

4. Possible side effects

NIVAZEN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NIVAZEN. 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:

- if you experience raised or fluid-filled skin spots over a large area of your body.

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

Tell your doctor if you notice any of the following:

Adults 18 years of age and older

Frequent

- headache,
- diarrhoea, nausea, vomiting,
- rash, pruritus,
- 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.

Less frequent

- 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,
- decrease in white blood cells, decrease in blood platelet count,

- low blood sugar,
- agitation, anxiety, depression, tremor,
- irregular heart rate, 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.

Frequency unknown

- hallucinations,
- decreased consciousness,
- altered mental status (including aggression, delirium, disorientation, mental status changes),
- abnormal movements,
- muscle weakness,
- unsteady walking,
- teeth staining.

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

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

Less frequent

- 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.

Frequency unknown

- hallucinations,
- altered mental status (including aggression).

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NIVAZEN.

5. How to store NIVAZEN

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- Do not use after the expiry date stated on the label and carton.

Reconstitution: Only a trained health care professional should prepare the solution for injection.

Once NIVAZEN 1 g has been prepared, it should be used straight away. Do not use NIVAZEN 1 g if you notice particles in the solution or the solution changes colour (it should be a clear colourless solution). Do not freeze solutions of NIVAZEN.

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 NIVAZEN contains

- The active substance is ertapenem.

Each vial contains ertapenem sodium equivalent to 1,0 g ertapenem.

The reconstituted solution contains 100 mg/ml ertapenem. Sugar free.

- The other ingredients are sodium bicarbonate and sodium hydroxide.

What NIVAZEN looks like and contents of the pack

NIVAZEN contains a sterile, pyrogen-free white to yellowish powder.

After reconstitution: A clear solution free from visible particles.

NIVAZEN is packed in a 20 ml glass vial with rubber stopper and flip-off seal.

Pack size: one vial is packed in an outer cardboard carton.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

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This leaflet was last revised in**Registration number**

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Access to the corresponding Professional Information

To be confirmed