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IVERZAM P1541714

IVERZAM P1541714

Professional Information for Medicines for Human Use

SCHEDULING STATUS

S4

PROPRIETARY NAME (and dosage form):

IVERZAM (powder for concentrate for solution for infusion)

COMPOSITION:
IVERZAM: Each vial contains 1.046 g of ertapenem sodium equivalent to 1 g ertapenem.
The other ingredients of **IVERZAM** are sodium bicarbonate and sodium hydroxide.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Pharmacological properties
Ertapenem is a sterile, synthetic, long acting, parenteral, 1-β methyl-carbapenem that is structurally related to beta-lactam antibiotics, such as penicillins and cephalosporins, with activity against a wide range of Gram-positive and Gram-negative aerobic and anaerobic bacteria.
The bactericidal activity of ertapenem results from the inhibition of cell wall synthesis and is mediated through ertapenem binding to penicillin binding proteins (PBPs). In *Escherichia coli*, it has strong affinity toward PBPs 1a, 1b, 2, 3, 4 and 5 with preference for PBPs 2 and 3. Ertapenem has significant stability to hydrolysis by most classes of beta-lactamases, including penicillinases, and cephalosporinases and extended spectrum beta-lactamases, but not metallo-beta-lactamases.

Resistant organisms
Corynebacterium spp., *Enterococcus* spp. (including *Enterococcus faecalis* and *Enterococcus faecium*), methicillin resistant *Staphylococcus aureus*, methicillin resistant coagulase negative *Staphylococcus*, *Acinetobacter* spp., *Pseudomonas* spp., *Stenotrophomonas maltophilia.*

Pharmacokinetic properties
Absorption
Ertapenem, reconstituted with 1 % lidocaine (lignocaine) hydrochloride injection USP (in saline without epinephrine (adrenaline)), is well absorbed following intramuscular (IM) administration at the recommended dose of 1 g. The mean bioavailability is approximately 92 %. Following 1 g daily IM administration, mean peak plasma concentrations (C_{max}) are reached in approximately 2 hours (T_{max}).

Distribution
Ertapenem is highly bound to human plasma proteins. In healthy young adults, the protein binding of ertapenem decreases as plasma concentrations increase, from approximately 95 % bound at an approximate plasma concentration of less than 100 µg/mL to approximately 85 % bound at an approximate plasma concentration of 300 µg/mL.
Average plasma concentrations (µg/mL) of ertapenem following a single 30-minute intravenous (IV) infusion of a 1 g or 2 g dose and IM administration of a single 1 g dose in healthy young adults showed that the area under the plasma concentration curve (AUC) of ertapenem in adults increases nearly dose-proportionally over the 0,5 g to 2 g dose range.
There is no accumulation of ertapenem in adults following multiple IV doses ranging from 0,5 g to 2 g daily or IM doses of 1 g daily.
Average plasma concentrations (µg/mL) of ertapenem in paediatric patients showed that the volume of distribution at steady state (V_{dss}) of ertapenem in adults is approximately 8 L (0,11 L/kg) and approximately 0,2 L/kg in paediatric patients 3 months to 12 years of age and approximately 0,16 L/kg in paediatric patients 13 to 17 years of age.
Ertapenem penetrates into suction-induced skin blisters. The ratio of AUC in skin blister fluid to AUC in plasma is 0,61.

The level of ertapenem in breast milk of 5 lactating women was measured at random time points daily for 5 consecutive days following the last 1 g dose of IV therapy. The measured concentration of ertapenem in breast milk on the last day of therapy (5 to 14 days postpartum) in all 5 women was less than 0,38 µg/mL; peak concentrations were not assessed. By day 5 after discontinuation of therapy, the level of ertapenem was undetectable in the breast milk of 4 women and was detected at trace levels (less than 0,13 µg/mL) in 1 woman.

In vitro studies indicate that ertapenem does not inhibit P-glycoprotein-mediated transport of digoxin or vinblastine and that ertapenem is not a substrate for P-glycoprotein-mediated transport (see **INTERACTIONS**).

Metabolism
In healthy young adults, after IV infusion of radio labelled 1 g ertapenem, the plasma radioactivity consists predominantly (94 %) of ertapenem. The major metabolite of ertapenem is the ring-opened derivative formed by hydrolysis of the beta-lactam ring.
In vitro studies in human liver microsomes indicate that ertapenem does not inhibit metabolism mediated by any of the six major cytochrome P450 (CYP) isoforms: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4.

Elimination
Ertapenem is eliminated primarily by the kidneys. The mean plasma half-life in healthy young adults and patients 13 to 17 years of age is approximately 4 hours and approximately 2,5 hours in paediatric patients 3 months to 12 years of age.
Following administration of a 1 g radio labelled IV dose of ertapenem to healthy young adults, approximately 80 % is recovered in urine and 10 % in faeces. Of the 80 % recovered in urine, approximately 38 % is excreted as unchanged drug and approximately 37 % as the ring-opened metabolite.
In healthy young adults given a 1 g IV dose, average concentrations of ertapenem in urine exceeded 984 µg/mL during the period 0 to 2 hours post administration and exceeded 52 µg/mL during the period 12 to 24 hours post adminstration.

Special populations
Elderly
Plasma concentrations following a 1 g and 2 g IV dose of ertapenem are slightly higher (approximately 39 % and 22 % respectively) in elderly adults (65 years or older) relative to young adults (younger than 65 years). No dosage adjustment is necessary in elderly patients.

Paediatric patients
Plasma concentrations of ertapenem are comparable in paediatric patients 13 to 17 years of age and adults following a 1 g once daily IV dose.
Following the 20 mg/kg dose (up to a maximum dose of 1 g), the pharmacokinetic parameter values in patients 13 to 17 years of age were generally comparable to those in healthy young adults.
Plasma concentrations at the midpoint of the dosing interval following a single 15 mg/kg IV dose of ertapenem in patients 3 months to 12 years of age are comparable to plasma concentrations at the midpoint of the dosing interval following a 1 g once daily IV dose in adults (see **Distribution**).

Hepatic insufficiency
The pharmacokinetics of ertapenem in patients with hepatic insufficiency have not been established. Due to the limited extent of hepatic metabolism of ertapenem, its pharmacokinetics are not expected to be affected by hepatic impairment. Therefore, no dosage adjustment is necessary in patients with hepatic impairment.

Renal insufficiency
Following a single 1 g IV dose of ertapenem in adults, AUC is similar in patients with mild renal insufficiency (Cl_{cr} 60 to 90 mL/min/1,73 m^2) compared with healthy subjects (aged 25 to 82 years). AUC is increased in patients with moderate renal insufficiency (Cl_{cr} 31 to 59 mL/min/1,73 m^2) approximately 1,5 fold compared with healthy subjects. AUC is increased in patients with advanced renal insufficiency (Cl_{cr} 5 to 30 mL/min/1,73 m^2) approximately 2,6 fold compared with healthy subjects. AUC is increased in patients with end stage renal insufficiency (Cl_{cr} less than 10 mL/min/1,73 m^2) approximately 2,9 fold compared with healthy subjects. Following a single 1 g IV dose given immediately prior to a haemodialysis session, approximately 30 % of the dose is recovered in the dialysate. There is no data in paediatric patients with renal insufficiency.
A dosage adjustment is recommended for patients with advanced or end-stage renal insufficiency (see **DOSAGE AND DIRECTIONS FOR USE**).

INDICATIONS:
IVERZAM is indicated for the treatment of adult patients with the following moderate to severe infections caused by susceptible strains of the designated micro-organisms (see **DOSAGE AND DIRECTIONS FOR USE**):
Complicated intra-abdominal infections due to *Escherichia coli, Clostridium clostridioforme, Eubacterium lentum, Peptostreptococcus* spp, *Bacteroides fragilis, Bacteroides distasonis, Bacteroides ovatus, Bacteroides thetaiotaomicron,* or *Bacteroides uniformis.*

Complicated skin and skin structure infections including diabetic lower extremity and diabetic foot infections due to *Staphylococcus aureus* (methicillin susceptible strains only), *Streptococcus agalactiae, Streptococcus pyogenes, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Porphyromonas asaccharolytica* or *Peptostreptococcus* spp.

Community acquired pneumonia due to *Streptococcus pneumoniae* (penicillin susceptible strains only) including cases with concurrent bacteraemia, *Moraxella catarrhalis*. If community acquired pneumonia is caused by *Haemophilus influenza*e, **IVERZAM** should only be used following confirmation of culture and sensitivity results.

Complicated urinary tract infections including pyelonephritis due to *Escherichia coli,* including cases with concurrent bacteraemia or *Klebsiella pneumoniae.*

Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynaecologic infections due to *Streptococcus agalactiae, Escherichia coli, Bacteroides fragilis, Porphyromonas asaccharolytica, Peptostreptococcus* spp or *Prevotella bivia.*

Paediatric use
Safety and efficacy of **IVERZAM** in paediatric patients 3 months to 17 years of age are supported by evidence from adequate and well-controlled studies in adults, pharmacokinetic data in paediatric patients and additional data from comparator-controlled studies in paediatric patients 3 months to 17 years of age with the following infections (see **DOSAGE AND DIRECTIONS FOR USE**).
- *Complicated intra-abdominal infections*
- *Complicated skin and skin structure infections*
- *Community acquired pneumonia*
- *Complicated urinary tract infections*
- *Acute pelvic infections*

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to **IVERZAM**. Therapy with **IVERZAM** may be initiated empirically before results of these tests are known; once results become available, antimicrobial therapy should be adjusted accordingly.

CONTRAINDICATIONS:
IVERZAM is contraindicated in patients with known bacterial meningitis and hypersensitivity to any component of **IVERZAM** or to other medicines in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactams.
IVERZAM, when administered intramuscularly with lidocaine (lignocaine) hydrochloride diluent, is contraindicated in patients with a known hypersensitivity to local anaesthetics of the amide type and in patients with severe shock or heart block.

IVERZAM is not recommended in the treatment of meningitis due to lack of sufficient cerebrospinal fluid (CSF) penetration.

WARNINGS AND SPECIAL PRECAUTIONS:
SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS HAVE BEEN REPORTED IN PATIENTS RECEIVING THERAPY WITH BETA-LACTAMS. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE HYPERSENSITIVITY REACTIONS WHEN TREATED WITH ANOTHER BETA-LACTAM. BEFORE INITIATING THERAPY WITH IVERZAM, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OTHER BETA-LACTAMS AND OTHER ALLERGENS. IF AN ALLERGIC REACTION TO IVERZAM OCCURS, DISCONTINUE IVERZAM IMMEDIATELY. SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE/ADRENALINE, OXYGEN, INTRAVENOUS STEROIDS AND AIRWAY MANAGEMENT, INCLUDING INTUBATION. OTHER THERAPY MAY ALSO BE ADMINISTERED AS INDICATED.

Seizures and other central nervous system (CNS) adverse experiences have been reported during treatment with **IVERZAM**.

Pseudomembranous colitis (antibiotic-associated colitis) has been reported with nearly all antibacterial medicines, including IVERZAM, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial medicines.
Treatment with antibacterial medicines alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-associated colitis".
After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to **IVERZAM** discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial medicine clinically effective against *Clostridium difficile* colitis.
Lidocaine (lignocaine) hydrochloride is the diluent for IM administration of **IVERZAM**.
During clinical investigations in adult patients treated with **IVERZAM** (1 g once a day), seizures, irrespective of medicine relationship, occurred in 0,5 % of patients during study therapy plus 14 day follow-up period. These experiences have occurred most commonly in patients with CNS disorders (e.g. brain lesions or history of seizures) and/or compromised renal function. Close adherence to the recommended dosage regimen is urged, especially in patients with known factors that predispose to convulsive activity. Anticonvulsant therapy should be continued in patients with known seizure disorders. If focal tremors, myoclonus or seizures occur, patients should be evaluated neurologically, placed on anticonvulsant therapy if not already instituted, and the dosage of **IVERZAM** re-examined to determine whether it should be decreased or the antibiotic discontinued. Dosage adjustment of **IVERZAM** is recommended in patients with reduced renal function (see **DOSAGE AND DIRECTIONS FOR USE**).
As with other antibiotics, prolonged use of **IVERZAM** may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.
There have been reports of drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) after the use of **IVERZAM**.
IVERZAM is more stable to renal dehydropeptidase I than imipenem and use with cilastatin, which inhibits the enzyme, is not required.
IVERZAM should not be given to patients known to be hypersensitive to it and should be given with caution to patients known to be hypersensitive to penicillins, cephalosporins or other beta lactams because of the possibility of cross-sensitivity.
It should be given with caution to patients with renal impairment and the dose reduced appropriately.
Particular care is necessary in patients with CNS disorders such as epilepsy.
IVERZAM is not recommended in infants under 3 months of age as no data is available.

Effects on ability to drive and use machines
There is no data to suggest that **IVERZAM** affects the ability to drive and operate machinery. Due to the possibility of the side effects such as dizziness, seizures and altered mental status occurring, the patient should be advised not to drive or operate any heavy machinery until the effect of **IVERZAM** on the patient is known.

INTERACTIONS:
Probenecid inhibits the renal excretion of **IVERZAM** thereby increasing its plasma concentrations and prolonging its elimination half-life.
In vitro studies indicate that ertapenem does not inhibit P-glycoprotein-mediated transport of digoxin or vinblastine and that ertapenem is not a substrate for P-glycoprotein-mediated transport. *In vitro* studies in human liver microsomes indicate ertapenem does not inhibit metabolism mediated by any of the six major cytochrome P450 (CYP) isoforms: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4. Drug interactions caused by inhibition of P-glycoprotein-mediated drug clearance or CYP-mediated drug clearance are unlikely (see **Pharmacokinetic properties**).
No specific clinical drug interaction studies have been conducted.
Decreased serum levels of valproic acid with co-administration of ertapenem have been reported as post-marketing experiences. Careful monitoring of serum levels of valproic acid should be considered if ertapenem is to be co-administered with valproic acid.

PREGNANCY AND LACTATION:
Safety in pregnancy has not been established.
IVERZAM is excreted in breast milk (see **Pharmacokinetic properties**, **Distribution**). Safety in nursing mothers has not been established.

DOSAGE AND DIRECTIONS FOR USE:
The usual dose of **IVERZAM** in patients age 13 years and older is 1 g given once a day.
The usual dose of **IVERZAM** in patients 3 months to 12 years of age is 15 mg/kg twice daily (not to exceed 1g/day).
IVERZAM may be administered by IV infusion or IM injection. When administered intravenously, **IVERZAM** should be infused over a period of 30 minutes.
IM administration of **IVERZAM** may be used as an alternative to IV administration in the treatment of those infections for which IM therapy is appropriate.
The usual duration of therapy with **IVERZAM** is 3 to 14 days but varies by the type of infection and causative pathogen(s) (see **INDICATIONS**). When clinically indicated, a switch to an appropriate oral antimicrobial may be implemented if clinical improvement has been reported.

Dosage guidelines for adults and paediatric patients with normal renal function* and body weight			
Infection	Daily dose (IV or IM) Adults and paediatric patients 13 years of age and older	Daily dose (IV or IM) Paediatric patients 3 months to 12 years of age	Recommended duration of total antimicrobial treatment
Complicated intra-abdominal Infection	1 g	15 mg/kg twice daily§	5 to 14 days
Complicated skin and skin structure infections including diabetic lower extremity and diabetic foot infections	1 g	15 mg/kg twice daily§	7 to 14 days†↓
Community acquired pneumonia	1 g	15 mg/kg twice daily§	10 to 14 days†
Complicated urinary tract infections including pyelonephritis	1 g	15 mg/kg twice daily§	10 to 14 days†
Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynaecologic infections	1 g	15 mg/kg twice daily§	3 to 10 days

* Defined as creatinine clearance greater than 90 mL/min/1,73 m^2
† Duration includes a possible switch to an appropriate oral therapy once clinical improvement has been demonstrated.
§ Not to exceed 1 g per day
↓ Patients with diabetic foot infections received up to 28 days of treatment (parenteral or parenteral plus oral switch therapy)

In controlled clinical studies, patients were treated from 3 to 14 days. Total treatment duration was determined by the treating medical practitioner based on site and severity of the infection and on the patient's clinical response. In some studies, treatment was converted to oral therapy at the discretion of the treating medical practitioner after clinical improvement had been demonstrated.

Patients with renal insufficiency
IVERZAM may be used for the treatment of infections in adult patients with renal insufficiency. In patients whose creatinine clearance is greater than 30 mL/min/1,73 m^2, no dosage adjustment is necessary. Adult patients with advanced renal insufficiency (creatinine clearance less than or equal to 30 mL/min/1,73 m^2), including those on haemodialysis, should receive 500 mg daily. There is not data available for paediatric patients with renal insufficiency.

Patients on haemodialysis
In a clinical study, following a single 1 g IV dose of **IVERZAM** given immediately prior to a haemodialysis session, approximately 30 % of the dose was recovered in the dialysate. When adult patients on haemodialysis are given the recommended daily dose or 500 mg of **IVERZAM** within 6 hours prior to haemodialysis, a supplementary dose of 150 mg is recommended following the haemodialysis session. If **IVERZAM** is given at least 6 hours prior to haemodialysis, no supplementary dose is needed. There is no data available for patients undergoing peritoneal dialysis or haemofiltration
There is no data available for paediatric patients on haemodialysis.
When only the serum creatinine is available, the following formula** may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function.

$$\text{Males: } \frac{\text{(weight in kg) x (140 – age in years)}}{\text{serum creatinine (µmol/L)}}$$

Females: (0,85) x (value calculated for males)

**Cockcroft and Gault equation: Cockcroft DW, Gault MH, Prediction of creatinine clearance from serum creatinine, Nephron. 1976

No dosage adjustment is recommended in patients with impaired hepatic function (see **Pharmacokinetic properties**, **Special population, Hepatic insufficiency**).
The recommended dose of **IVERZAM** can be administered without regard to age (13 years of age and older) or gender.

INSTRUCTIONS FOR USE
Patients 13 years of age and older
Preparation for IV administration:
DO NOT MIX OR CO-INFUSE **IVERZAM** WITH OTHER MEDICINES.
DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).
IVERZAM MUST BE RECONSTITUTED AND THEN DILUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of **IVERZAM** with 10 mL of one of the following: Water for Injection, 0,9 % Sodium Chloride Injection (154 mmol/L) or Bacteriostatic Water for Injection using a syringe equipped with a 21-guage or smaller diameter needle.
2. Shake well to dissolve and immediately transfer contents of the reconstituted vial to 50 mL of 0,9 % Sodium Chloride Injection (154 mmol/L).
3. Complete the infusion within 6 hours of reconstitution.

Preparation for IM administration:
IVERZAM MUST BE RECONSTITUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of **IVERZAM** with 3,2 mL of 1,0 % or maximum 3,2 mL of 2,0 % lidocaine (lignocaine) hydrochloride injection (**without epinephrine**). Shake vial thoroughly to form solution. This represents the maximum recommended dose of lidocaine.
2. Immediately withdraw the contents of the vial and administer by deep IM injection into a large muscle mass (such as the gluteal muscles or lateral part of the thigh).
3. The reconstituted IM solution should be used within 1 hour after preparation.

Note: This reconstituted solution for IM administration should not be administered IV.

Paediatric patients 3 months to 12 years of age
Preparation for IV administration:
DO NOT MIX OF CO-INFUSE **IVERZAM** WITH OTHER MEDICINES.
DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).
IVERZAM MUST BE RECONSTITUTED AND THEN DILUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of **IVERZAM** with 10 mL of one of the following: Water for Injection, 0,9 % Sodium Chloride Injection (154 mmol/L) or Bacteriostatic Water for Injection using a syringe equipped with a 21-guage or smaller diameter needle.
Note: Use with a needleless IV system is not recommended. The resultant concentration is approximately 100 mg/mL.
2. Shake well to dissolve and immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) and dilute in 0,9 % Sodium Chloride Injection (154 mmol/L) to a final concentration of 20 mg/mL or less.
3. Complete the infusion within 6 hours of reconstitution.

Preparation for IM administration:
IVERZAM MUST BE RECONSTITUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of **IVERZAM** with 3,2 mL of 1,0 % or maximum 3,2 mL of 2,0 % lidocaine (lignocaine) hydrochloride injection (**without epinephrine**). Shake vial thoroughly to form solution. This represents the maximum recommended dose of lidocaine.
2. Immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) and administer by deep IM injection into a large muscle mass (such as the gluteal muscles or lateral part of the thigh).
3. The reconstituted IM solution should be used within 1 hour after preparation.

Note: This reconstituted solution for IM administration should not be administered IV.

Parenteral pharmaceutical products should be inspected visually for particulate matter and discoloration prior to use, whenever solution and container permit. Solutions of **IVERZAM** range from colourless to pale yellow. Variations of colour within this range do not affect the potency of the product.

SIDE EFFECTS:
Immune system disorders:
Less frequent: Allergic reaction
Frequency unknown: Anaphylaxis including anaphylactoid reactions

Psychiatric disorders:
Frequent: Altered mental status

Nervous system disorders:
Frequent: Headache
Less frequent: Seizures, anxiety, dizziness, insomnia
Frequency unknown: Hallucinations

Cardiac disorders:
Less frequent: Tachycardia

Vascular disorders:
Frequent: Infused vein complication
Less frequent: Phlebitis or thrombophlebitis, hypertension, hypotension

Respiratory, thoracic and mediastinal disorders:
Less frequent: Cough, dyspnoea or respiratory distress, pharyngitis

Gastrointestinal disorders:
Frequent: Diarrhoea, nausea
Less frequent: Pseudomembranous colitis, constipation, dyspepsia, oral candidiasis, vomiting, acid regurgitation

Skin and subcutaneous tissue disorders:
Less frequent: Erythema, pruritus, rash

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Leg pain

Reproductive system and breast disorders:
Less frequent: Vaginitis

Investigations:
Frequent: Elevated alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, platelet count, decrease in neutrophil count
Less frequent: Increase in direct serum bilirubin, total serum bilirubin, eosinophils, indirect serum bilirubin, Partial Thromboplastin Time, urine bacteria, serum urea, serum creatinine, serum glucose, monocytes, urine epithelial cells, urine red blood cells, decreases in segmented neutrophils, white blood cells, haematocrit and haemoglobin

General disorders and administrative site conditions:
Frequent: Chest pain, fever
Less frequent: Asthenia or fatigue, oedema

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Treatment
In the event of an overdose, **IVERZAM** should be discontinued and general supportive treatment given until renal elimination takes place.
IVERZAM can be removed by haemodialysis; however, no information is available on the use of haemodialysis to treat overdosage.

IDENTIFICATION:
White to off white lyophilised cake or powder. When reconstituted, it is a clear colourless to pale yellow solution free from particles.

PRESENTATION:
20 mL clear transparent type-I glass tubular vial of 20 mm neck stoppered with 20 mm grey bromobutyl rubber stopper and sealed with 20 mm white aluminium PP disc.

Pack sizes:
1. Single vial packed in a printed carton with package insert.
2. 10 vials packed in a plain E-fluted box with partition and package insert.

STORAGE INSTRUCTIONS:
Lyophilised powder:
Store at or below 25 °C.

Reconstituted solutions:
IV use: The reconstituted solution, immediately diluted in 0,9 % of sodium chloride injection, may be stored at room temperature (25 °C) and used within 6 hours or stored for 24 hours under refrigeration (5 °C) and used within 4 hours after removal from refrigeration.
IM use: The reconstituted solution should be used within 1 hour after preparation.
Solutions of **IVERZAM** should not be frozen. Any unused portion of solutions of **IVERZAM** should be discarded.

STORE ALL VIALS OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
51/20.1.1/0745

HOLDER OF THE CERTIFICATE OF REGISTRATION:
AUROGEN SA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
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17 March 2020

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31 January 2023

PATIENT INFORMATION LEAFLET

S4

IVERZAM (powder for concentrate for solution for infusion)
Ertapenem

Read all of this leaflet carefully before you are given IVERZAM.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **IVERZAM** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT IVERZAM CONTAINS
The active ingredient is ertapenem.
IVERZAM:
Each vial contains 1,046 g of ertapenem sodium equivalent to 1 g ertapenem.
The other ingredients of **IVERZAM** are sodium bicarbonate and sodium hydroxide.

2. WHAT IVERZAM IS USED FOR
IVERZAM is an antibiotic which contains a medicine called ertapenem.
IVERZAM is used to treat bacterial infections which may be moderate or severe and which are caused by particular micro-organisms. It is used particularly in conditions such as complicated infections within your abdomen, skin or skin structure infections such as foot infections which diabetic patients are prone to, pneumonia, complicated urinary tract infections and infections of your pelvis.

3. BEFORE YOU ARE GIVEN IVERZAM
You should not be given IVERZAM:
- if you are hypersensitive (allergic) to ertapenem or to any of the ingredients of **IVERZAM**.
- if you have previously suffered with bacterial meningitis (inflammation of the tissues that surround the brain or spinal cord).
- if you have previously had a serious allergic reaction to other antibiotics. You should tell your doctor about this as it may indicate whether you will be allergic to **IVERZAM** as well.
- if you have previously had an allergic reaction to any local anaesthetics or if you have suffered from severe shock or if you know you have a slow heart rate, you should tell your doctor as you may not be able to be given **IVERZAM** with certain anaesthetics.

Take special care with IVERZAM:
- **you must tell your doctor if you have previously had a serious allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash) to other antibiotics (penicillin, cephalosporin, other beta-lactams) or any other type of medicine, as it may suggest that you are allergic to IVERZAM as well.**
- if you suffer from seizures or impaired kidney function it may make you more prone to having fits while on treatment with **IVERZAM**.
- if you experience severe diarrhoea after being given **IVERZAM** it may indicate that you have another infection of your colon caused by **IVERZAM**. You should notify your doctor of this so that the correct treatment can be started as soon as possible.

Pregnancy and breastfeeding:
Safety has not been determined during pregnancy and breastfeeding. **IVERZAM** is however excreted in breast milk and is therefore not recommended if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving **IVERZAM.**

Driving and using machinery:
Due to the possibility of side effects such as dizziness, seizures and altered mental status occurring, you should not drive or operate any heavy machinery until you know what effect **IVERZAM** has on you.

Taking other medicines with IVERZAM:

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).
- Probenecid, a medicine typically used to treat gout, may delay the excretion of **IVERZAM** from your body, therefore making the effect last longer.
- **IVERZAM** may decrease your blood levels of valproic acid, a medicine used in the treatment of fits, if taken together. Therefore your doctor may need to monitor your blood levels if you are given **IVERZAM**.

4. HOW TO RECEIVE IVERZAM
The usual dose of **IVERZAM** in patients 13 years of age and older is 1 gram (g) given once a day.
The usual dose of **IVERZAM** in patients 3 months to 12 years of age is 15 mg/kg twice daily (not to exceed 1 g/day).
The treatment duration will last from 3 to 14 days depending on the type of infection that you have.

IVERZAM can be administered directly into your muscle or into your veins. If it is administered directly into your vein, it will be done over a period of 30 minutes.

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

If you have been given more IVERZAM than you should:

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

4. POSSIBLE SIDE EFFECTS
IVERZAM can have side effects.

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

If any of the following happen, tell your doctor immediately or go to the casualty department at your nearest hospital:
- an allergic reaction with symptoms such as swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

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

Tell your doctor immediately if you notice any of the following:
- fits
- chest pain
- diarrhoea
- increased or decreased blood pressure
- increase in heart rate
- dizziness
- changes in your mental wellbeing.

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

Tell your doctor if you notice any of the following:
- headache
- anxiety
- difficulty sleeping
- hallucinations
- cough
- difficulty breathing
- nausea
- fever
- acid reflux
- itchy red rash
- leg pain
- tiredness, and loss of muscle strength
- constipation
- oral fungal infection.

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

5. STORING AND DISPOSING OF IVERZAM

Lyophilised powder:
Store at or below 25 °C.

Reconstituted solutions:
Intravenous (IV) use: The reconstituted solution, immediately diluted in 0,9 % of sodium chloride injection, may be stored at room temperature (25 °C) and used within 6 hours or stored for 24 hours under refrigeration (5 °C) and used within 4 hours after removal from refrigeration.
Intramuscular (IM) use: The reconstituted solution should be used with in 1 hour after preparation.
Solutions of **IVERZAM** should not be frozen. Any unused portion of solutions of **IVERZAM** should be discarded.

STORE ALL VIALS OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. PRESENTATION OF IVERZAM

20 mL clear transparent type-I glass tubular vial of 20 mm neck stoppered with 20 mm grey bromobutyl rubber stopper and sealed with 20 mm white aluminium PP disc.

Pack sizes:
1. Single vial packed in a printed carton with package insert.
2. 10 vials packed in a plain E-fluted box with partition and package insert.

7. IDENTIFICATION OF IVERZAM

White to off white lyophilised cake or powder. When reconstituted, it is a clear colourless to pale yellow solution free from particles.

8. REGISTRATION NUMBER

51/20.1.1/0745

9. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen SA (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
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PASIËNTINLIGTINGSBLAD

S4

IVERZAM (poeier vir konsentraat vir oplossing vir infusie)
Ertapenem

Lees hierdie hele blaadjie noukeurig deur voordat IVERZAM aan u toegedien word.
- Hou hierdie blaadjie. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, vra asseblief vir u dokter of u apteker.
- **IVERZAM** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

1. WAT IVERZAM BEVAT
Die aktiewe bestanddeel is ertapenem.
IVERZAM:
Elke flessie bevat 1,046 g van ertapenem natrium ekwivalent aan 1 g ertapenem.
Die ander bestanddele van **IVERZAM** is natriumbikarbonaat en natriumhidroksied.

2. WAARVOOR IVERZAM GEBRUIK WORD
IVERZAM is 'n antibiotikum wat 'n medisyne, wat ertapenem genoem word, bevat.
IVERZAM word gebruik om matige tot ernstige bakteriële infeksies wat deur spesifieke mikroörganismes veroorsaak word, te behandel. Dit word veral in toestande soos gekompliseerde infeksies in die buik, vel- of velstruktuurinfeksies soos voetinfeksies wat dikwels by diabete voorkom, longontsteking of gekompliseerde urienweginfeksies en bekkeninfeksies gebruik.

3. VOORDAT U IVERZAM ONTVANG:
Moenie IVERZAM ontvang nie:
- as u hipersensitief (allergies) teenoor ertapenem of enige ander bestanddeel van **IVERZAM** is.
- as u voorheen aan bakteriële meningitis (inflammasie van die weefsels rondom die brein en rugmurg) gely het.
- as u voorheen 'n ernstige allergiese reaksie teenoor ander antibiotika gehad het. U moet u dokter daaroor inlig, aangesien dit 'n aanduiding kan wees dat u ook teenoor **IVERZAM** allergies sal wees.
- as u voorheen 'n allergiese reaksie teenoor enige lokale verdowingsmiddel gehad het of as u aan erge skok gely het, of as u weet dat u 'n stadige hartklop het, behoort u u dokter daaroor in te lig, aangesien dit miskien nie moontlik sal wees om **IVERZAM** saam met sekere verdowingsmiddels aan u toe te dien nie.

Wees besonder versigtig met IVERZAM:
- **u moet u dokter daaroor inlig as u voorheen 'n ernstige allergiese reaksie (soos swelling van die gesig, tong of keel, moeite met asemhaling of sluk, veluitslag) teenoor ander antibiotika (penisillien, kefalosporien, ander beta-laktame) of enige ander soort medisyne getoon het, aangesien dit mag aandui dat u ook teen IVERZAM allergies is.**
- as u aan stuipe-aanvalle of ingekorte nierfunksie ly, mag dit u meer vatbaar vir stuipe-aanvalle maak as u op behandeling met **IVERZAM** is.
- as u erge diarree ondervind nadat **IVERZAM** aan u toegedien is, mag dit aandui dat u 'n ander infeksie van u kolon het wat deur **IVERZAM** veroorsaak is. U behoort u dokter in kennis te stel as dit die geval is sodat daar so gou moontlik met die korrekte behandeling begin kan word.

Swangerskap en borsvoeding:
Die veiligheid is nie in swangerskap en borsvoeding vasgestel nie. **IVERZAM** word in borsmelk uitgeskei en daarom word dit nie aanbeveel dat u u baba borsvoed nie.

As u swanger is of u baba borsvoed, moet u asseblief met u dokter, apteker of ander gesondheidskundige praat voordat u **IVERZAM** ontvang.

Bestuur en die gebruik van masjinerie:
As gevolg van die moontlikheid van newe effekte soos duiseligheid, stuipe-aanvalle en 'n verandering in geestestoestand, behoort u nie motor bestuur of enige swaar masjinerie hanteer totdat u weet watter effek **IVERZAM** op u het nie.

Gebruik van ander medisyne saam met IVERZAM :

Stel altyd u gesondheidskundige daarvan in kennis as u enige ander medisyne gebruik (dit sluit aanvullende of tradisionele medisyne in).

- Probenesied, 'n medisyne wat tipies gebruik word om jig te behandel, mag die uitskeiding van **IVERZAM** uit u liggaam vertraag, wat die effek langer laat duur.
- **IVERZAM** mag die bloedvlakke van valproësuur, 'n medisyne vir die behandeling van stuipe-aanvalle verlaag as hulle gelyktydig geneem word. Daarom mag dit vir u dokter nodig wees om u bloedvlakke te kontroleer as **IVERZAM** aan u toegedien word.

4. HOE OM IVERZAM TE ONTVANG
Die normale dosis van **IVERZAM** by pasiënte van 13 jaar oud en ouer is 1 gram (g) wat een keer per dag toegedien word.
Die normale dosis van **IVERZAM** by pasiënte van 3 maande tot 12 jaar oud is 15 mg/kg twee keer per dag (1 g per dag moet nie oorskry word nie).
Die behandeling sal van 3 tot 14 dae duur, afhangend van die soort infeksie waaraan u ly.

IVERZAM kan direk in u spier of aar toegedien word. Indien dit direk in die aar toegedien word, sal dit oor 'n periode van 30 minute geskied.

Daar sal nie van u verwag word om **IVERZAM** self toe te dien nie. Dit sal deur 'n persoon wat gekwalifiseerd is om dit te doen, gedoen word.

As u te veel IVERZAM ontvang het:

Aangesien 'n gesondheidskundige **IVERZAM** sal toedien, sal hy/sy die dosis kontroleer. In die geval van oordosering sal 'n dokter egter die oordosering bestuur.

5. MOONTLIKE NEWE EFFEKTE

IVERZAM kan newe effekte hê.

Nie al die newe effekte wat vir **IVERZAM** aangemeld is, word in hierdie blaadjie ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **IVERZAM** ontvang, moet u asseblief u dokter, apteker of ander gesondheidskundige vir advies raadpleeg.

Indien u enige van die volgende ervaar, moet u dadelik vir u dokter sê, of na die ongevalle-afdeling van u naaste hospitaal gaan:
- 'n allergiese reaksie met simptome soos swelling van die hande, voete, enkels, gesig, lippe, mond of tong wat moeite met sluk en asemhaling veroorsaak.

Hierdie is almal baie ernstige newe effekte. As hulle voorkom, kon u moontlik 'n ernstige allergiese reaksie teenoor **IVERZAM** gehad het. U mag dringende mediese aandag nodig hê.

Indien u enige van die volgende opmerk:
- stuipe-aanvalle
- borspyn
- diarree
- toename of afname in bloeddruk
- toename in harttempo
- duiseligheid
- veranderinge in u geestestoestand.

Hierdie is almal baie ernstige newe effekte. U mag dringende mediese aandag nodig hê.

Sê dadelik vir u dokter indien u enige van die volgende opmerk:
- hoofpyn
- angs
- moeite met slaap
- hallusinasies
- hoes
- moeite met asemhaling
- naarheid
- koors
- suurrefluks
- jeukerige rooi uitslag
- beenpyn
- moegheid en verlies aan spierkrag
- hardlywigheid
- swaminfeksies van die mond.

Indien u enige newe effekte opmerk wat nie in hierdie blaadjie genoem word nie, raadpleeg asseblief u dokter of apteker.

6. BEWARING EN WEGDOENING VAN IVERZAM
Gevriesdroogde poeier:
Bewaar by of benede 25 °C.

Hersaamgestelde oplossings:
Intraveneuse (IV) gebruik: Die hersaamgestelde oplossing wat onmiddellik in 0,9 % natriumchloried inspuiting verdun is, kan teen kamertemperatuur (25 °C) bewaar en binne 6 uur gebruik word, of vir 24 uur onder verkoeling (5 °C) bewaar word en binne 4 uur na verwydering uit die yskas gebruik word.
Intramuskulêre (IM) gebruik: Gebruik die hersaamgestelde oplossing behoort binne 1 uur na voorbereiding.
Oplossings van **IVERZAM** behoort nie gevries te word nie. Enige ongebruikte gedeelte van die oplossing behoort weggedoen te word.

BEWAAR ALLE FLESSIES BUITE BEREIK VAN KINDERS.

Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

7. AANBIEDING VAN IVERZAM
'n Helder 20 mL deursigtige tipe-I buisvormige glasflessie met 'n 20 mm nek en 20 mm grys bromobutiel rubberprop, geseël met 'n 20 mm wit aluminium PP skyfie.

Pakgrootte:
1. n Enkel flessie in n voorafgedrukte kartondosie met n voubiljet.
2. 10 flessies verpak in n ongedrukte E-gegroefde boks met afskorting en n voubiljet

8. IDENTIFIKASIE VAN IVERZAM
Wit tot naaswit gevriesdroogde koekie of poeier. Wanneer hersaamgestel, is dit 'n kleurlose tot liggeelgekleurde oplossing, vry van deeltjies.

9. REGISTRASIENOMMER
51/20.1.1/0745

9. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
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