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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Cefepime and Amikacin For Injection Along with Solvent for Cefepime and Amikacin for Injection

POTENTOX®
PERSISTENT IN ACTION

625 mg, 1.25 g, 2.5 g

For I.V. Use Only

DESCRIPTION

POTENTOX is a novel Antibiotic Adjuvant Entity (AAE) of cefepime hydrochloride, amikacin sulphate and a chemical vector available as sterile dry powder for reconstitution before use. Potentox for Injection is supplied for slow intravenous administration in 0.625 g, 1.25 g and 2.5 g strengths of Potentox in which cefepime & amikacin is in the ratio of 4:1. Cefepime hydrochloride, is a semi-synthetic, broad spectrum, cephalosporin antibiotic for parenteral administration. Amikacin sulphate is a semi-synthetic aminoglycoside antibiotic derived from kanamycin. The chemical vector (L-arginine) at an approximate concentration of 40% is added to make them chemically compatible and control the pH of constituted solution at 4.5 to 7.5. The combination dosage form is supplied as sterile powder for IV use only.

Each vial contains: 625 mg Potentox: Cefepime Hydrochloride I.P. equivalent to Cefepime 500 mg, Amikacin Sulphate I.P. equivalent to Amikacin 125 mg, L-Arginine (on dried basis) I.P. 185 mg

Each vial contains: 1.25 g Potentox: Cefepime Hydrochloride I.P. equivalent to Cefepime 1000 mg, Amikacin Sulphate I.P. equivalent to Amikacin 250 mg, L-Arginine (on dried basis) I.P. 370 mg

Each vial contains: 2.5 g Potentox: Cefepime Hydrochloride I.P. equivalent to Cefepime 2000 mg, Amikacin Sulphate I.P. equivalent to Amikacin 500 mg, L-Arginine (on dried basis) I.P. 740 mg

Solvent: Each ml contains: Sodium Chloride I.P. 0.45 mg, Potassium Chloride I.P. 2 mg, Water for Injections I.P. qs to 1 mL

CLINICAL PHARMACOLOGY

Pharmacokinetics

Absorption: Potentox is to be administered intravenously. The maximum plasma concentration of cefepime and amikacin after 30 min infusion was 84.097SD ± 14.035 µg/mL and 15.34 SD ± 4.142 µg/mL, respectively.

Table 1: Pharmacokinetic parameters after intravenous infusion of 1.25 g Potentox

Pharmacokinetic parameter	Cefepime	Amikacin
Half-life (h)	2.048 ± 0.642	2.090 ± 0.421
Elimination rate constant (h^{-1})	0.3609 ± 0.0874	0.3442 ± 0.0688
T_{max} (h)	0.557 ± 0.141	0.508 ± 0.055
AUC_{0-t} (µg*h/mL)	172.443 ± 30.129	28.613 ± 5.973
$AUC_{0-\infty}$ (µg*h/mL)	182.467 ± 30.808	29.399 ± 12.930
C_{max} (µg/mL)	84.097 ± 14.035	15.345 ± 4.142

Results expressed as mean ± SD

Distribution: The average steady-state volume of distribution is 18 ± 2 L and 24 ± 4 L and serum protein binding is 20% and 0 to 11% for cefepime and amikacin respectively.

Metabolism and excretion: Cefepime present in Potentox is metabolized to N-methylpyrrolidine (NMP) and rapidly converted to the N-oxide (NMP-N-oxide). Elimination of cefepime is principally via renal excretion with an average half-life of 2 ± 0.3 hour (h) and total body clearance of 120 ± 8 mL/min. Amikacin present in Potentox is not metabolized. Small amounts (1 to 2% of the dose) are excreted in the bile, while the remainder (98 to 99%) is excreted in the urine via glomerular filtration. Elimination of amikacin is principally via renal excretion with an average half-life of 2-3 h and total body clearance of 100 mL/min.

MECHANISM OF ACTION

Potentox is an AAE of cefepime and amikacin. Cefepime, like other β-lactams, inhibits bacterial cell wall biosynthesis and impedes the final transpeptidation step of peptidoglycan synthesis. Unlike other extended-spectrum cephalosporins, the methylpyrrolidinium group of cefepime confers a zwitterionic charge that enhances bactericidal activity by rapid penetration through the porin channels in the outer membrane of Gram-negative pathogens. Amikacin binds to the aminoacyl site of 16S ribosomal RNA within the 30S ribosomal subunit, leading to misreading of the genetic code and inhibition of translocation. The initial steps required for peptide synthesis are uninterrupted, such as binding of mRNA and the association of the 50S ribosomal subunit but elongation fails to occur due to disruption of the mechanisms for ensuring translational accuracy. Binding interferes with mRNA binding and tRNA acceptor sites leading to the production of non-functional or toxic peptides.

The synergistic action of Potentox allows 10 x MIC to be maintained more than 10 h compared to maximum of 3 h with individual drug. The post antibiotic effect PAE ranges from 4-8 h for various above described clinical pathogen isolates. Therefore on whole, adding the BD regimen for Potentox is supported, because the inhibitory concentrations for Potentox are maintained in range of 11-17 h compared to only 3-10 h for individual drugs.

MICROBIOLOGY

Potentox is active against wide range of gram-negative, multi-drug resistant pathogens including aminoglycoside & flouroquinolone resistant microorganisms. Potentox® exhibits synergistic activity against *QnrA, qnrB, qnrS, aac(6)-Ie-aph(2)-Ia, ant(4)-Ia* and *aph(2)-Id* genes expressing strains.

Gram-negative aerobes: *Acinetobacter* spp., *Aeromonas hydrophila, Capnocytophaga* spp., *Citrobacter* spp., *Campylobacter jejuni, Cardnerella vaginalis, Enterobacter* spp., *Escherichia coli, Haemophilus* spp. (including strains producing betalactamase), *Hafnia alvei, Klebsiella* spp., *Legionella* spp., *Morganella morganii, Moraxella catarrhalis* (including strains producing betalactamase). *Neisseria gonorrhoeae* spp., *Proteus* spp., *Pseudomonas* spp., *Salmonella* spp., *Serratia* spp., *Shigella* spp., *Yersinia enterocolitica.* Some strains of *Stenotrophomonas maltophilia* can be resistant.

Gram-Positive aerobes: *Staphylococcus aureus, Staphylococcus epidermidis, S. saprophyticus, Streptococcus pyogenes* (A group streptococcus); *Streptococcus agalactiae* (B group streptococcus), *Streptococcus pneumoniae, Viridans group streptococci.*

Anaerobes: *Bacteroides* spp. except *Bacteroides fragilis,* including *B. melaninogenicus* and other oral cavity microorganisms referred to bacteroides; *Clostridium perfringens; Fusobacterium* spp.*; Mobiluncus* spp.*; Peptostreptococcus* spp.*; Veillonella* spp. Potentox is not active against *Bacteroides fragilis* and *Clostridium difficile.*

Susceptibility testing methods: As recommended with all antimicrobials, the results of in vitro susceptibility tests, when available, should be provided to the physician as a periodic reports, which describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports would aid the physician in selecting the most effective antimicrobial.

Diffusion techniques: Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. This procedure uses paper disks impregnated with 30 µg of Cefepime and 7.5 µg of Amikacin to test the susceptibility of microorganisms to Potentox.

Table 2. Susceptibility interpretive criteria for Potentox against different cultures (> 500 isolates of each species used in the study).

Pathogens	Minimum inhibitory concentration (µg/ml)			Disk diffusion (Zone diameter in mm)		
	Susceptible	Intermediate	Resistant	Susceptible	Intermediate	Resistant
Enterobacteriaceae	≤8	16	≥32	≥19	16-18	≤15
Pseudomonas spp.	≤8	16	≥32	≥18	15-17	≤14
Non-*Enterobacteriaceae*	≤8	16	≥32	≥18	15-17	≤14

where Susceptible (S) indicates that the pathogen is likely to respond to therapy; Intermediate (I) indicates that the result should be considered equivocal. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where a high dosage of drug can be used. Resistant (R) suggests that the pathogen is not likely to respond to the therapy.

INDICATIONS

Potentox is indicated in the treatment of the following infections caused by the multidrug resistant strains found susceptible to Potentox. It is mainly indicated in the severe bacterial infection like

- Lower respiratory tract infections (LRTI): Nosocomial and community acquired pneumonia
- Febrile Neutropenia

Other indications: Skin and skin structure infections caused by gram negative MDR pathogens, Surgical Procedures, Complicated intra-abdominal infections, Bone and joint infection, Diabetic patients undergoing surgeries, Acute bronchitis, Complicated urinary tract infections, Abscess, Traumatic & Accidental Cases, Sepsis

DOSAGE AND ADMINISTRATION

Mode of administration

Adult Dose: Mild to moderate infection = Potentox 1.25 g twice daily over 30-60 min infusion time for 5 to 7 days Severe or life threatening infection = Potentox 2.5 g twice daily over 30-60 min infusion time 5 to 7 days

Elderly: These dosages do not require modification in elderly patients provided that renal and hepatic functions are satisfactory.

Impaired hepatic function: No adjustment is necessary for patients with impaired hepatic function.

Impaired renal function: There is no need to adjust dosage in the elderly unless renal impairment is present. Cefepime component is excreted by the kidneys almost exclusively by glomerular filtration. Therefore, in patients with impaired renal function (creatinine clearance ≤ 50 mL/min), the dose of Potentox should be adjusted to compensate for the slower rate of renal elimination. The recommended initial dose of Potentox in patients with mild to moderate renal impairment should be the same as in patients with normal renal function. An estimate of creatinine clearance should be made to determine the appropriate maintenance dose. The recommended initial dose for patients on hemodialysis and maintenance doses of Potentox in patients with renal insufficiency are presented in following Table 3.

Table 3: Dosage recommendation for Potentox in adult patients with renal impairment

Renal status of the patient	Potentox dose recommendation (Original dose 2.5/1.25/0.625 g)		
	Cefepime (g)	Amikacin (g)	Fold reduction and Potentox dose
Normal (GFR>90 mL/min/1.73m^2 or CrCL>50 mL/min)	2.0/1.0/0.50	0.50/0.25/0.125	None
Mild impairment (GFR 60-89 mL/min/1.73m^2 or CrCL 30-50 mL/min)	1.2/0.60/0.30	0.30/0.15/0.075	0.6 times the normal dose 1.5/0.75/0.375 g
Moderate impairment (GFR 50-59 mL/min/1.73m^2 or CrCL 11-29 mL/min)	1.0/0.50/0.25	0.25/0.125/0.0625	0.5 times the normal dose 1.25/0.625/0.3125 g
Severe impairment (GFR 15-29 mL/min/1.73m^2 or CrCL <11 mL/min)	0.80/0.40/0.20	0.20/0.10/0.050	0.4 times the normal dose 1.0/0.5/0.25g
Recommendations based on simulation of renally compromised patient pharmacokinetics and doses extrapolated to achieve exposure equivalent to patient with normal renal function status			

When only serum creatinine measurement is available, the following formula (proposed by Cockcroft and Gault) may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function:

$$\text{Males: creatinine clearence (mL/min)} = \frac{\text{Weight (kg) x (140 - age)}}{\text{72 x serum creatinine (mg / dL)}}$$

Table 4: Dose of Potentox in Pediatrics (625 mg)

Mild to Moderate Infections

625 mg of Potentox = 5 mL of solution						
Severity of Infections	**Dose (mL)**	**Weight**	**Dose (mL) in two divided doses**	**Potentox Dose (mg)**	**Cefepime/day (ideal dose range for Cefepime (60-100 mg/kg/day in 2 to 3 divided dose)**	**(Amikacin/day (Ideal dose range for Amikacin (15- 20 mg/kg/day in 2 to 3 divided dose)**
Mild to Moderate Infections	**0.35/kg**	3 kg	2.1 mL	262.5 mg	210 mg	52.5 mg
		4 kg	2.8 mL	350 mg	280 mg	70 mg
		5 kg	3.5 mL	437.5 mg	350 mg	87.5 mg
		6 kg	4.2 mL	525 mg	424 mg	101 mg
		7 kg	4.9 mL	612.5 mg	492 mg	120.5 mg
		8 kg	5.6 mL	700 mg	560 mg	140 mg
		9 kg	6.3 mL	787.5 mg	630 mg	157.5 mg
		10 kg	7 mL	941 mg	770 mg	171 mg

Stability time for vial is 2-8 ºC

MDR & Severe Infections

625 mg of Potentox = 5 mL of solution						
Severity of Infections	**Dose (mL)**	**Weight**	**Dose (mL) in two divided doses**	**Potentox Dose (mg)**	**Cefepime/day (ideal dose range for Cefepime (100-150 mg/kg/day in 2 to 3 divided dose)**	**(Amikacin/day (Ideal dose range for Amikacin (20- 30 mg/kg/day in 2 to 3 divided dose)**
MDR & Severe Infections	**0.5/kg**	3 kg	3 mL	375 mg	300 mg	75 mg
		4 kg	4 mL	500 mg	400 mg	100 mg
		5 kg	5 mL	625 mg	500 mg	125 mg
		6 kg	6 mL	750 mg	600 mg	150 mg
		7 kg	7 mL	874 mg	700 mg	174 mg
		8 kg	8 mL	1000 mg	800 mg	200 mg
		9 kg	9 mL	1124 mg	900 mg	224 mg
		10 kg	10 mL	1250	1000 mg	250 mg

Stability time for vial is 2-8 ºC

Pediatric patients with impaired renal function: Since urinary excretion is the primary route of elimination of cefepime in pediatric patients, an adjustment of the dosage of Potentox should also be considered in this population. A dose of 62.5 mg/kg in patients aged 2 months up to 12 years (for severe cases) is comparable to a dose of 2.5 g in an adult. As recommended in above Table, the same dose modification and/or reduction in dose should be used. For mild to mederate cases, a dose of 43.75 mg/kg twice a day is recommended. When only serum creatinine is available, creatinine clearance may be estimated using either of the following methods.

$$\text{Creatinine clearence (mL/min/1.73 m}^2\text{)} = \frac{\text{0.55 x height (centimeters)}}{\text{serum creatinine (mg / dL)}}$$

or

$$\text{Creatinine clearence (mL/min/1.73 m}^2) = \left[\frac{0.55 \times \text{height (centimeters)}}{\text{serum creatinine (mg / dL)}}\right] - 3.6$$

Duration of therapy: The usual duration of Potentox treatment is from 3 to 10 days. In all conditions, the duration of therapy should be guided by the severity of the infection and the patient's clinical and bacteriological progress.

INCOMPATIBILITY AND STABILITY

Solutions of Potentox, should not be added to solutions of ampicillin at a concentration greater than 40 mg/mL and should not be added to Metronidazole, Vancomycin, Gentamicin, Tobramycin, Netimicin sulfate or Aminophylline because of potential interaction. However, if concurrent therapy with Potentox® is indicated, each of these antibiotics can be administered separately. The color of Potentox powder, as well as its solutions, tend to darken depending on storage conditions; however, when stored as recommended, the product potency is not adversely affected.

RECONSTITUTION AND ADMINISTRATION

Reconstitution procedure: Reconstitute Potentox powder for injection/infusion with solvent provided with pack and then with any of infusion solutions like 5% dextrose, 10% dextrose, DNS, Ringer lactate, M/6 Sodium lactate, Maintenance solution M and R where it remains stable for 6 h at room temperature. Administer the solution via intravenous route. Cleanse the injection site with a new alcohol swab prior to administration. However, the use of freshly prepared solutions is recommended.

For intravenous infusion, constitute the 625 mg in 5 mL, 1.25 g in 10 mL or 2.5 g in 20 mL with solvent supplied with the pack and add resulting solution to an IV container with one of the compatible IV fluids. The resulting solution should be administered over approximately 30-60 minutes. Table 5 below provides instructions for use.

Table 5: Reconsitution and administration for use

Product strength (g)	Volume of solvent for IV use (mL)	Cefepime/Amikacin Concentration (mg/mL)	Qty of reconstituted solution in ml having 35mg/kg dose	For 15kg body weight	For 30kg body weight	For 60kg body weight
0.625	5	100 / 25	0.28 mL	4.2 mL	—	—
1.25	10	100 / 25	0.28 mL	4.2 mL	8.4 mL	—
2.5	20	100 / 25	0.2 mL	4.2 mL	8.4 mL	16.8 mL

The procedures above are provided as general guidelines for the reconstitution and administration of Potentox. Always work on a clean surface and wash your hands before performing the following procedures. Reconstitution, product administration and handling of the administration set must be done with caution.

DRUG INTERACTIONS

As the individual component of the product has neuro, nephro and/or ototoxicity related issues. Drugs that can worsen these toxicities need to be avoided. The concurrent use of Cefepime-Amikacin with potent diuretics (ethacrynic acid or frusemide) should be avoided as it may enhance amino glycoside toxicity by altering antibiotic concentrations in serum and tissue.

Drug/laboratory test interactions: It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix) be used.

CONTRAINDICATIONS

Potentox is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or cephalosporin class of antibiotics or amikacin or any other aminoglycoside, penicillins or other beta-lactam antibiotics.

WARNINGS

Hypersensitivity reactions: Before therapy with Potentox for Injection is instituted, careful inquiry should be made to determine whether the patient has had previous immediate hypersensitivity reactions to cefepime, cephalosporins,

penicillin or other drugs. If an allergic reaction to Potentox occurs, discontinue the drug. The use of Potentox in patients with a history of allergy to aminoglycosides or in patients who may have sub-clinical renal or eighth nerve damage induced by prior administration of nephrotoxic and/or ototoxic agents such as streptomycin, dihydrostreptomycin, gentamicin, tobramycin, kanamycin, neomycin, polymyxin B, colistin, cephaloridine or viomycin should be considered with caution, as toxicity may be additive. In these patients amikacin should be used only if, in the opinion of the physician, therapeutic advantages outweigh the potential risks.

Use in patients with renal impairment: In patients with creatinine clearance less than or equal to 60 mL/min, adjust the dose of Potentox.

Neurotoxicity: Neurotoxicity related to Amikacin and Cefepime might be observed. If neurotoxicity associated with Potentox therapy occurs, consider discontinuing Potentox or making appropriate dosage adjustments as in patients with renal impairment.

Neuromuscular toxicity: Potentox should be used with caution in patients with muscular disorders such as myasthenia gravis or Parkinsonism since these drugs may aggravate muscle weakness because of their potential curare-like effect on the neuromuscular junction.

Use in pregnant woman: Aminoglycosides can cause fetal harm when administered to a pregnant woman by crossing the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Reproduction studies of Potentox have been performed in rats and mice and revealed no evidence of impaired fertility or harm to the fetus due to amikacin at recommended dosage regimens.

Clostridium difficile: *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefepime and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile. C. difficile* produces toxins A and B which contribute to the development of CDAD. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile* and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General: Prescribing Potentox in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Many cephalosporins, including cefepime, have been associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Positive direct Coombs' tests have been reported during treatment with cefepime. Cefepime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Carcinogenesis, mutagenesis, impairment of fertility: The mutagenicity of Potentox was evaluated by two mutagenicity tests, the reverse mutation assay in bacteria and the chromosomal aberration test with Chinese hamster CHL cells and was found non-mutagenic. Reproductive toxicity study of Potentox® in rats showed no impairment of fertility.

Nursing mothers: Caution should be exercised when Potentox is administered to a nursing woman.

Labor and delivery: Potentox has not been studied for use during labor and

delivery.

Geriatric use: Serious adverse events have occurred in geriatric patients with renal insufficiency.

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and renal function should be monitored.

Amikacin injection is potentially nephrotoxic, ototoxic. The concurrent or serial use of other ototoxic or nephrotoxic agents should be avoided with Potentox, because of the potential for additive effects.

Potentox should be used with caution in patients with muscular disorders such as myasthenia gravis or parkinsonism as these drugs may aggravate muscle weakness due to their potential curare-like effect on the neuromuscular junction.

Cross-allergenicity among aminoglycosides has been demonstrated. As with other antibiotics, the prolonged under dose/use of Potentox may result in overgrowth of nonsusceptible organisms. If this occurs, appropriate therapy should be instituted. Potentox should not be given concurrently with potent diuretics.

ADVERSE REACTIONS

Potentox is generally well tolerated. The majority of adverse events is of mild or moderate severity and is tolerated with continued treatment. In Phase-III clinical trial few adverse events observed are Gastrointestinal disorders include diarrhoea/loose stool, nausea and vomiting. General disorder and administration site conditions include pain at site of injection, local phlebitis. Besides above said reactions, further adverse reactions known with individual active components which may be observed with Potentox.

OVERDOSAGE

The signs of the drug overdosage includes appearance of skin rash, scab, fever, nausea, vomiting. In case of renal insufficiency, peritoneal dialysis or hemodialysis will aid in the removal of drug from the body.

Accidental overdosing may occur when large doses are given to patients with impaired renal function. Other symptoms of overdose include encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor and coma), myoclonus, seizures and neuromuscular excitability.

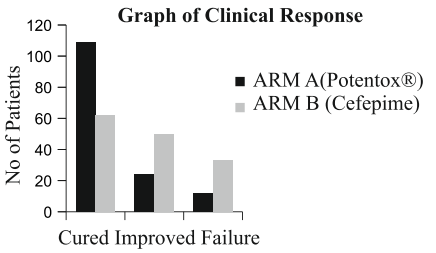
CLINICAL STUDIES

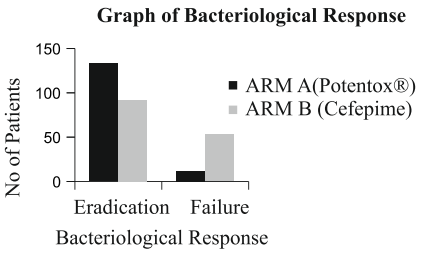
Open label, multicentric, randomized comparative clinical trial was conducted to evaluate the efficacy and safety of Potentox (2.5 g) versus cefepime (2.0 g) in the treatment of nosocomial pneumonia given IV, twice daily (n = 290).

Clinical response: In treatment arm A, of 145 enrolled subjects, 109 (75.17 %) subjects showed complete clinical cure in terms of total relief and absence of any disease symptoms and 24 (16.56%) subjects shown significant improvement in the clinical symptoms, when compared from baseline to completion of the protocol therapy and 12 (8.27%) subjects were considered as treatment failures as they failed to respond to the protocol therapy at day 3. In treatment arm B (cefepime) of total 145 subjects, 62 (42.76 %) subjects shown complete clinical cure, 50 (34.48%) subjects shown significant improvement in the clinical symptoms, when compared from baseline to completion and 33 (22.76%) subjects were considered as treatment failures (29 subjects failed to respond to therapy at day 3 and 4 subjects not responded even after completion of adequate therapy).

Bacteriological response: In Treatment arm A, of 145 positive in Sputum/BAL culture subjects, 133 (91.72%) subjects were reported to achieve complete bacteriological eradication, however 12 (8.28%) subjects were reported as treatment failure (Treatment received <5 days). In treatment arm B, of 145 subjects, who reported positive in sputum/BAL culture, 92 (63.45%) subjects were reported to achieved complete bacteriological eradication; 53 (36.55%)

subjects were reported as treatment failure.





Post-marketing surveillance study: During PMS study, data of approximately 311 patients were collected in routine clinical practice across different centers in India and evaluated for safety and efficacy. The reported AEs were pain at injection site 05 (1.60%), Skin rash 04 (1.28%), Diarrhoea 01 (0.32%), Vomiting 04 (1.28%) and Chills 01 (0.32%). All the events were mild to moderate in severity and resolved without sequale. In tolerably assessment 62.1% patients have very good response, 34.7% patient has good response, 2.9% patients has fair response and only 0.3% patient had not well tolerated response.

STORAGE

Potentox in the dry state should be stored between 20°C-25°C (68°F-77°F) and protected from direct light. Keep out of reach of children. The reconstituted solution is stable up to 8 h at room temperature (25ºC) and up to 24 h at 2°C-8°C. Shelf life - 24 months without reconstitution when stored at recommended storage conditions.

PACKAGING INFORMATION

Potentox is supplied as a sterile dry powder in glass vials and comes in a unit carton pack containing one vial of dry powder for injection along one vial of solvent with package insert. Potentox 0.625 g vial is supplied with 5 mL of solvent, Potentox 1.25 g vial with 10 mL of solvent and Potentox 2.5 g vial with 20 mL of solvent.

HANDLING DISPOSAL

Parentral drug products should be inspected visually for particulate matter and discoloration prior to administration when ever the solution and container permit. Any unused product or waste material should be disposed of in accordance with local requirements.

Patent Protected Research Product of Venus Medicine Research Centre

Indian Patent No: 235775, US Patent No: 8178501, EU Patent No: 1861110

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