Nivador® Injection
(Ceftazidime)

For intramuscular or intravenous use

DESCRIPTION:
Nivador® (Ceftazidime) is a semisynthetic, broad-spectrum, beta-lactam antibiotic for parenteral administration that belongs to cephalosporin 3rd generation. The empirical formula is $C_{22}H_{32}N_6O_{12}S_2$ with a molecular weight of 636.6g

COMPOSITION:
Nivador® **250mg Injection:**
Each vial contains:
Sterile powder of Ceftazidime Pentahydrate USP
equivalent to Ceftazidime.....250mg

Nivador® **500mg Injection:**
Each vial contains:
Sterile powder of Ceftazidime Pentahydrate USP
equivalent to Ceftazidime.....500mg

Nivador® **1g Injection:**
Each vial contains:
Sterile powder of Ceftazidime Pentahydrate USP
equivalent to Ceftazidime.....1g

PHARMACOLOGY:
Mode of Action:
Ceftazidime is bactericidal and have the same mode of action as other beta-lactam antibiotics (Such as penicillins). Ceftazidime acts by inhibiting synthesis of the bacterial cell wall. Bacterial cell walls are held rigid and protected against osmotic rupture by peptidoglycan. Ceftazidime inhibits the final cross linking stage of peptidoglycan production by binding to and inactivating transpeptidase, which is a penicillin binding protein on the inner surface of the bacterial cell membrane

PHARMACOKINETICS:
Parenteral administration produces high and prolonged serum levels; mean peak plasma concentrations of 17 and 39µg per ml was achieved approximately one hour after intramuscular administration of 0.5 and 1g of ceftazidime respectively. Five minutes after intravenous bolus injections of 0.5 and 1gm of ceftazidime , mean plasma concentrations of 45 and 90µg per ml respectively, have been reported. The plasma half life of ceftazidime is about 2 hours, but this is prolonged in patients with renal impairment and in neonates. Plasma protein binding of ceftazidime is about 10%

Ceftazidime is widely distributed in body tissues and fluids' therapeutic concentrations are achieved in the CSF when the meninges are inflamed. It crosses the placenta and is distributed into breast milk
Ceftazidime is passively excreted in bile , although only a small proportion is eliminated by this route. It is mainly excreted through kidney about 80 to 90% of a dose is recovered unchanged in the urine within 24 hours, It is removed by haemodialysis and peritoneal dialysis

MICROBIOLOGY:
Ceftazidime has been shown to be active against the following organisms both in vitro and in clinical infections

Aerobes, Gram-negative: Citrobacter spp., including Citrobacter freundii and Citrobacter diversus; Enterobacter spp., including Enterobacter cloacae and Enterobacter aerogenes; Escherichia coli; Haemophilus influenzae, including ampicillin-resistant strains; Klebsiella spp. (Including Klebsiella pneumoniae); Neisseria meningitidis; Proteus mirabilis; Proteus vulgaris; Pseudomonas spp. (Including Pseudomonas aeruginosa); and Serratia spp.

Aerobes, Gram-positive: Staphylococcus aureus, including penicillinase and non–penicillinase producing strains; Streptococcus agalactiae (Group B Streptococci); Streptococcus pneumoniae; and Streptococcus pyogenes (Group A beta-hemolytic Streptococci)

Anaerobes: Bacteroides spp. (**Note:** Many strains of Bacteroides fragilis are resistant)

INDICATIONS AND USAGE:
Nivador® is indicated for the treatment of patients with infections caused by susceptible strains of the designated organisms in the following diseases:

1. Lower Respiratory Tract Infections, including pneumonia, caused by Pseudomonas aeruginosa and other Pseudomonas spp.; Haemophilus influenzae, including ampicillin-resistant strains; Klebsiella spp.; Enterobacter spp.; Proteus mirabilis; Escherichia coli; Serratia spp.; Citrobacter spp.; Streptococcus pneumoniae; and Staphylococcus aureus (Methicillin-susceptible strains)

2. Skin and Skin-Structure Infections caused by Pseudomonas aeruginosa; Klebsiella spp.; Escherichia coli; Proteus spp., including Proteus mirabilis and indole-positive Proteus; Enterobacter spp.; Serratia spp.; Staphylococcus aureus (Methicillin-susceptible strains); and Streptococcus pyogenes (Group A beta-hemolytic Streptococci)

3. Urinary Tract Infections, both complicated and uncomplicated, caused by Pseudomonas aeruginosa; Enterobacter spp.; Proteus spp., including Proteus mirabilis and indole-positive Proteus; Klebsiella spp.; and Escherichia coli

4. Bacterial Septicemia caused by Pseudomonas aeruginosa, Klebsiella spp., Haemophilus influenzae, Escherichia coli, Serratia spp., Streptococcus pneumoniae, and Staphylococcus aureus (Methicillin-susceptible strains)

5. Bone and Joint Infections caused by Pseudomonas aeruginosa, Klebsiella spp., Enterobacter spp., and Staphylococcus aureus (Methicillin-susceptible strains)

6. Gynecologic Infections, including endometritis, pelvic cellulitis, and other infections of the female genital tract caused by Escherichia coli

7. Intra-abdominal Infections, including peritonitis caused by Escherichia coli, Klebsiella spp., Staphylococcus aureus (Methicillin-susceptible strains) and polymicrobial infections caused by aerobic and anaerobic organisms and Bacteroides spp. (Many strains of Bacteroides fragilis are resistant)

8. Central Nervous System Infections, including meningitis, caused by Haemophilus influenzae and Neisseria meningitidis. Ceftazidime has also been used successfully in a limited number of cases of meningitis due to Pseudomonas aeruginosa and Streptococcus pneumoniae

CONTRAINDICATIONS:
Nivador® is contraindicated in-patients who have shown hypersensitivity to ceftazidime or the cephalosporin group of antibiotics

PRECAUTIONS:
Pregnancy
Teratogenic Effects: Pregnancy category B. This drug should be used during pregnancy only if clearly needed

Nursing Mothers: Ceftazidime is excreted in human milk in low concentrations therefore; caution should be exercised when it is administered to a nursing mother

Elderly Patients: The elimination of ceftazidime may be reduced due to impairment of renal function

DOSAGE AND ADMINISTRATION:
Nivador® (Ceftazidime for injection) may be administered either intravenously or intramuscularly after reconstitution. Dosage and route of administration should be determined by severity of infection, susceptibility of the causative organism(s), and condition of the patient
Adults: 1g to 6g IM or IV in 2 or 3 divided doses is generally used in patients with normal renal function
For less severe infections 500mg- 1g every 12 hours, moderate to severe infections 1g every 8 hours or 2g every 12hours. For most severe infections 2g every 8 or 12 hours is recommended

Infants and Children: 30-100mg/kg/day in 2 or 3 divided doses. Doses up to 150mg/kg/day (Maximum 6g/day) in three divided doses may be given to infected immuno comprised or fibrocystic children or children with meningitis

Neonates: In children aged one month or less the recommended dose is 25-50mg/kg of ceftazidime given twice daily

Use in Elderly: In acutely ill elderly patients with reduced renal clearance of ceftazidime, the daily dosage should not exceed 3gm

Impaired Hepatic Function: No adjustment in dosage is required for patients with hepatic dysfunction provided renal function is not impaired

Impaired Renal Function: In patients with impaired renal function the dosage of ceftazidime may need to be reduced. Following a loading dose of 1g, maintenance doses are based on the creatinine clearance

Suggested maintenance doses are:

For creatinine clearance 31 to 50ml per min	1g every 12 hours
For creatinine clearance 16 to 30ml per min	1g every 24 hours
For creatinine clearance 6 to 15ml per min	0.5g every 24 hours
For creatinine clearance < 5ml per min	0.5g every 48 hours

Nivador® may be given intravenously or by deep IM injection into a large muscle mass such as the upper outer quadrant of the gluteus maximus or lateral part of the thigh. Intra-arterial administration should be avoided

Injection Preparation:
For direct intramuscular injection reconstitute with sterile water for injection. Use 1.0ml, 1.5ml and 3.0ml for 250mg, 500mg and 1g respectively
For intravenous injection use sterile water for injection 2.5ml, 5ml and 10ml for 250mg, 500mg and 1g respectively
Effervescence occurs on addition of water for injection

Stability of the Reconstituted Solution:
Nivador® when constituted as directed with sterile water for injection maintains satisfactory potency for 12 hours at room temperature or for 3 days under refrigeration

AVAILABILITY:
Nivador® 250mg injection in a pack of 1 x 250mg vial + 5ml water for injection
Nivador® 500mg injection in a pack of 1 x 500mg vial + 5ml water for injection
Nivador® 1g injection in a pack of 1 x 1g vial + 10ml water for injection

STABILITY:
See expiry on the pack

INSTRUCTION:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30ºC
Improper storage may deteriorate the medicine

Manufactured for:
SAMI Pharmaceuticals (Pvt.) Ltd.
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www.samipharmapk.com

by:
Healthtek (Pvt.) Limited
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نیواڈور انجکشن
(سیفٹازیڈیم)

(برائے عضلاتی یا وریدی استعمال)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات: بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

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