Nixon™
Ceftriaxone

COMPOSITION
Nixon 250 mg IM/IV Injection: Each vial contains dry powder equivalent to 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and each ampoule contains 2 ml Lidocaine HCl USP1% injection for IM injection or 5 ml Water for injection USP for IV injection.
Nixon 500 mg IM/IV Injection: Each vial contains dry powder equivalent to 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and each ampoule contains 2 ml Lidocaine HCl USP1% injection for IM injection or 5 ml Water for injection USP for IV injection.
Nixon 1 g IM/IV Injection: Each vial contains dry powder equivalent to 1 g Ceftriaxone (as sterile Ceftriaxone Sodium EP) and each ampoule contains 3.5 ml Lidocaine HCl USP 1% injection for IM injection or 10 ml Water for injection USP for IV injection.
Nixon 2 g IV Injection: Each vial contains dry powder equivalent to 2 g Ceftriaxone (as sterile Ceftriaxone Sodium EP) and each of two ampoules contains 10 ml Water for injection USP for IV injection.

PHARMACOLOGY
Nixon contains Ceftriaxone which is a 3rd generation broad-spectrum parenteral cephalosporin antibiotic. It has potent bactericidal activity against a wide range of Gram-positive and Gram-negative organisms. Like other cephalosporins and penicillins, **Nixon** kills bacteria by interfering with the synthesis of the bacterial cell wall. **Nixon** has a high degree of stability in the presence of beta lactamases. A remarkable feature of **Nixon** is its relatively long plasma elimination half-life of about 6 to 9 hours, which makes single or once-daily dosage of the drug appropriate for most patients. **Nixon** is not metabolized in the body. About 40-65% of a dose of **Nixon** is excreted unchanged in the urine; the remainder is excreted in the bile and ultimately found in the feces as unchanged drug and microbiologically inactive compound. The drug is highly protein bound (95%).

INDICATION
Nixon is indicated for the treatment of the following major infections:
- Lower respiratory tract infections
- Acute Bacterial Otitis Media
- Skin and skin structure infections
- Urinary tract infections
- Gonorrhea
- Bacterial Septicemia
- Bone and joint infections
- Meningitis
- Prevention of postoperative infections
- Perioperative prophylaxis of infections associated with surgery

DOSAGE AND ADMINISTRATION
Adult: The usual dose is 1 to 2 gm by intravenous or intramuscular administration once a day (or in equally divided doses twice a day).

Indication	Dosage
Pneumonia, Bronchitis, Acute bacterial otitis media, Skin and skin structure infection, Urinary tract infections, Bacterial Septicemia, Bone and joint infections, Meningitis	1 to 2 g IV or IM once a day (or in equally divided doses twice a day); Maximum dose: 4 gm/day
Uncomplicated gonococcal infections	250 mg IM as a single dose
Surgical prophylaxis	1 g IV as a single dose 30 to 120 minutes before surgery

Infants and Children (01 month or older): The usual dose is 50 to 75 mg/kg intravenous or intramuscular administration once a day (or in equally divided doses twice a day).

Indication	Dosage
Pneumonia, Bronchitis, Skin and skin structure infection, Urinary tract infections, Bacterial Septicemia, Bone and joint infections.	50 to 75 mg/kg IV or IM once a day (or in equally divided doses twice a day); Maximum dose: 2 gm/day
Acute bacterial otitis media	50 mg/kg IM in single dose; Maximum dose: 1 gm/day
Meningitis	100 mg/kg IV or IM in single daily dose or (or in equally divided doses twice a day); Maximum dose: 4 gm/day

Duration of therapy: Continue for more than 2 days after signs and symptoms of infection have disappeared. Usual duration is 4 to 14 days; in complicated infections, longer therapy may be required.

Preparation of Solutions for Intramuscular / Intravenous Injections:
For Intramuscular Injection: 250 mg or 500 mg **Nixon** should be dissolved in 2 ml Lidocaine HCl USP 1% injection or 1 g **Nixon** in 3.5 ml of Lidocaine HCl USP 1% injection.
For Intravenous Injection: 250 mg or 500 mg **Nixon** should be dissolved in 5 ml of Water for injection USP or 1 g **Nixon** in 10 ml of Water for injection USP or 2 g **Nixon** in 20 ml of Water for injection USP.

The injection should be administered over 2-4 minutes, by Intramuscular or Intravenous injection or by tubing infusion over a period of 30 minutes at concentration between 10 mg/mL and 40 mg/mL. Before starting treatment through Ceftriaxone injection, patient tolerance test should be checked by administration of a test dose.

(The use of freshly reconstituted solution is recommended. However, it maintains potency for at least 6 hours at room temperature or 24 hours at 5°C).

CONTRAINDICATION
Ceftriaxone should not be given to patients with a history of hypersensitivity to cephalosporin antibiotics.

PRECAUTION
As with other cephalosporins, anaphylactic shock cannot be ruled out even if a thorough patient history is taken. Anaphylactic shock requires immediate countermeasures such as intravenous epinephrine followed by a glucocorticoid.
In rare cases, shadows suggesting sludge have been detected by sonograms of the gallbladder. This condition was reversible on discontinuation or completion of **Nixon** therapy. Even if such findings are associated with pain, conservative, nonsurgical management is recommended. During prolonged treatment the blood picture should be checked at regular intervals.

SIDE EFFECT
Nixon is generally well tolerated. A few side effects such as gastro-intestinal effects including diarrhea, nausea and vomiting, stomatitis and glossitis; cutaneous reactions including rash, pruritus, urticaria, edema and erythema multiforme; hematologic reactions including eosinophilia, thrombocytopenia, leucopenia, anemia and neutropenia; hepatic reactions including elevations of SGOT or SGPT, bilirubinemia; CNS reactions including nervousness, confusion, sleep disturbances, headache, hyperactivity, convulsion, hypertonia and dizziness were reported. Local phlebitis occurs rarely following intravenous administration but can be minimized by slow injections over 2-4 minutes.

USE IN PREGNANCY AND LACTATION
Its safety in human pregnancy has not been established. Therefore, it should not be used in pregnancy unless absolutely indicated. Low concentrations of Ceftriaxone are excreted in human milk. Caution should be exercised when **Nixon** is administered to a lactating mother.

USE IN CHILDREN
Nixon must not be given to neonates if the neonates is premature and newborn (up to 28 days of age).

DRUG INTERACTION
No drug interactions have been reported.

OVERDOSE
There is no specific antidote. Treatment of overdosage should be symptomatic.

STORAGE CONDITION
Keep in a dry place away from light and heat. Keep out of the reach of children.

PACKAGING
Nixon 250 mg IM Injection: Combipack of one vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 2 ml Lidocaine HCl USP 1% injection. It also contains a complementary pouch comprised of disposable syringe (3 ml), baby needle, alcohol pad and first aid bandage.
Nixon 250 mg IV Injection: Combipack of one vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 5 ml Water for injection USP. It also contains a complementary pouch comprised of disposable syringe (5 ml), alcohol pad and first aid bandage.
Nixon 500 mg IM Injection: Combipack of one vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 2 ml Lidocaine HCl USP 1% injection. It also contains a complementary pouch comprised of disposable syringe (3 ml), baby needle, alcohol pad and first aid bandage.
Nixon 500 mg IV Injection: Combipack of one vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 5 ml Water for injection USP. It also contains a complementary pouch comprised of disposable syringe (5 ml), alcohol pad and first aid bandage.
Nixon 1 g IM Injection: Combipack of one vial containing 1 g Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 3.5 ml Lidocaine HCl USP 1 % injection. It also contains a complementary pouch comprised of disposable syringe (5 ml), alcohol pad and first aid bandage.
Nixon 1 g IV Injection: Combipack of one vial containing 1 g Ceftriaxone (as sterile Ceftriaxone Sodium EP) and one ampoule of 10 ml Water for injection USP. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.
Nixon 2 g IV Injection: Combipack of one vial containing 2 g Ceftriaxone (as sterile Ceftriaxone Sodium EP) and two ampoules of 10 ml Water for injection USP. It also contains a complementary pouch comprised of disposable syringe (20 ml), butterfly needle, alcohol pad and first aid bandage.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.