

# Nixon

## Ceftriaxone

Nixon contains Ceftriaxone which is a 3<sup>rd</sup> 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%).

### COMPOSITION

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

### INDICATION

Nixon is indicated for the treatment of the following major infections:

- Renal and urinary tract infections
- Lower respiratory tract infections, particularly pneumonia
- Gonococcal infections
- Skin, soft tissue, bone and joint infections
- Bacterial meningitis
- Serious bacterial infections e.g. septicemia
- ENT infections
- Infections in cancer patients
- Prevention of postoperative infections
- Perioperative prophylaxis of infections associated with surgery
- Typhoid fever

### DOSAGE AND ADMINISTRATION

**Adult:** by deep intramuscular injection or by intravenous injection over at least 2-4 minutes, or by intravenous infusion, 1 g daily; 2-4 g daily in severe infections; intramuscular doses over 1 g divided between more than one site.

**Neonate:** by intravenous infusion over 60 minutes, 20-50 mg/kg daily (max. 50 mg/kg daily).

**Infant and child under 50 kg:** by deep intramuscular injection or by intravenous injection over 2-4 minutes or by intravenous infusion, 20-50 mg/kg daily; up to 80 mg/kg daily in severe infections; doses of 50 mg/kg and over by intravenous infusion only.

**50 kg and over:** adult dose.

**Uncomplicated gonorrhoea:** by deep intramuscular injection, 250 mg as a single dose.

**Surgical prophylaxis:** by deep intramuscular injection or by intravenous injection over at least 2-4 minutes, 1 g at induction.

**Colorectal surgery:** by deep intramuscular injection or by intravenous injection over at least 2-4 minutes or by intravenous infusion, 2 g at induction; intramuscular doses over 1 g divided between more than one site.

**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, directly into the vein or via the tubing of an intravenous infusion.

(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

**Use in pregnancy:** Its safety in human pregnancy has not been established. Therefore it should not be used in pregnancy unless absolutely indicated. Only minimal amount of Nixon is excreted in breast milk, so mother-receiving Nixon should not breast-feed.

### SIDE EFFECT

Ceftriaxone is generally well tolerated. A few side effects such as gastro-intestinal effects including diarrhoea, 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 headache, hyperactivity, nervousness, sleep disturbances, confusion, hypertension and dizziness were reported. Local phlebitis occurs rarely following intravenous administration but can be minimized by slow injections over 2-4 minutes.

### DRUG INTERACTION

No drug interactions have been observed with diuretics or with aminoglycosides.

### STORAGE CONDITION

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

### HOW SUPPLIED

**Nixon 250 mg IM Injection:** Combipack of one vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) 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 USP) 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 USP) 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 USP) 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 USP) 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 USP) 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 USP) 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.

Manufactured by:

**NIPRO**  
JMI Pharma

**NIPRO JMI Pharma Ltd.**  
Comilla, Bangladesh.