

# Axon

Ceftriaxone Sodium USP

## DESCRIPTION :

Axon is a third generation broad-spectrum parenteral cephalosporin antibiotic. It has potent bactericidal activity against a wide range of Gram-positive and Gram-negative organisms. Axon like other cephalosporins and penicillins kills bacteria by interfering with the synthesis of the bacterial cell wall. Axon has a high degree of stability in the presence of beta lactamases. Ceftriaxone is not metabolized in the body. About 40-65% of a dose of Ceftriaxone is excreted unchanged in the urine; the remainder is excreted in the bile and ultimately found in the faeces as unchanged drug and microbiologically inactive compound. The drug is highly protein bound (95%)

## COMPOSITION :

**Axon 250 mg IM Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 250 mg and 1 ampoule of 2 ml 1% Lidocaine Injection USP.

**Axon 250 mg IV Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 250 mg and 1 ampoule of 5 ml Water for Injection BP.

**Axon 500 mg IM Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 500 mg and 1 ampoule of 2 ml 1% Lidocaine Injection USP.

**Axon 500 mg IV Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 500 mg and 1 ampoule of 5 ml Water for Injection BP.

**Axon 1 g IM Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 1 g and 1 ampoule of 3.5 ml 1% Lidocaine Injection USP.

**Axon 1 g IV Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 1 g and 1 ampoule of 10 ml Water for Injection BP.

**Axon 2 g IV Injection:** Each vial contains sterile dry powder of ceftriaxone sodium USP equivalent to Ceftriaxone 2 g and 2 ampoules of 10 ml Water for Injection BP.

## INDICATIONS :

**Axon** is indicated for the treatment of the following major infections: 1. Renal and urinary tract infections 2. Lower respiratory tract infections, particularly pneumonia 3. Gonococcal infections 4. Skin, soft tissue, bone and joint infections 5. Bacterial meningitis 6. Serious bacterial infections e.g. septicemia 7. ENT infections 8. Infections in cancer patients 9. Prevention of postoperative infections 10. Perioperative prophylaxis of infections associated with surgery 11. Typhoid fever.

## DOSAGE & ADMINISTRATION:

**Adult:** by deep intramuscular injection, or by intravenous injection over at least 5 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 5 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 gonorrhea:** by deep intramuscular injection, 250 mg as a single dose. **Surgical prophylaxis:** by deep intramuscular injection or by intravenous injection over at least 5 minutes, 1 g at induction **Colorectal Surgery:** by deep intramuscular injection or by intravenous injection over at least 5 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  $\geq 2$  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 intravenous injection:** 250 mg or 500 mg **Axon** should be dissolved in 5 ml of water for injection BP or 1 g **Axon** in 10 ml of water for injection BP or 2 g **Axon** in 20 ml water for injection BP with vigorous shaking. A tolerability test should be performed by a test dose before administering the full dose into patient's body. Then the injection should be administered slowly over 5 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. Although the color becomes deep with time. **For intramuscular injection:** 250 mg or 500 mg **Axon** should be dissolved in 2 ml of 1% Lidocaine injection USP or 1 g **Axon** in 3.5 ml of 1% Lidocaine injection USP.

## CONTRAINDICATION :

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

## PRECAUTION:

Its safety in human pregnancy has not been established. Therefore it should not be used in pregnancy unless absolutely indicated. Only minimal amount of Ceftriaxone is excreted in breast milk, so mother-receiving Ceftriaxone should not breast-feed. In severe renal impairment accompanied by hepatic insufficiency, dosage reduction is required.

## ADVERSE REACTIONS :

Ceftriaxone is generally well tolerated. A few side effects such as gastro-intestinal effects including diarrhoea, nausea and vomiting, stomatitis & glossitis; cutaneous reactions including rash, pruritus, urticaria, oedema & 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, convulsion & involuntary movements, hypertonia and dizziness were reported. Local phlebitis occurs rarely following intravenous administration but can be minimized by slow injections over 5 minutes.

## DRUG INTERACTIONS:

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

## STORAGE :

- Store below 25°C
- Protect from light.
- Keep out of the reach of children.

## INCOMPATIBILITIES :

The admixture of beta-lactam antibacterials (penicillins and cephalosporins) and aminoglycosides may result in substantial mutual inactivation. If they are administered concurrently, they should be administered in separate sites. Do not mix them in the same intravenous bag or bottle.

## PACKING :

Axon is supplied as sterile powder in glass vial.

**Axon 250 mg IM Injection :** Combipack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 2 ml 1% Lidocaine Injection USP.

**Axon 250 mg IV Injection:** Combipack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 5 ml Water for Injection BP.

**Axon 500 mg IM Injection:** Combipack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 2 ml 1% Lidocaine Injection USP.

**Axon 500 mg IV Injection:** Combipack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 5 ml Water for Injection BP.

**Axon 1g IM Injection :** Combipack of 1 vial containing 1g Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 3.5 ml 1% Lidocaine Injection USP.

**Axon 1g IV Injection:** Combipack of 1 vial containing 1g Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 10 ml Water for Injection BP.

**Axon 2g IV Injection:** Combipack of 1 vial containing 2g Ceftriaxone and 2 ampoules of 10 ml Water for Injection BP.