

# ARTWORK FOR APPROVAL

Size: 150 mm x 120 mm

Board: \_\_\_\_\_

Grammage: \_\_\_\_\_

U/V: Print proof

Others: XXX-XXX

# Artwork for Approval New Size

1st Revised 18-05-2017

## PRESCRIBING INFORMATION

**INCETAX<sup>®</sup>** 0.25gm, 0.5gm &  
(Cefotaxime for Injection USP) 1.0gm Injection

انسیتیکس  
0.25 گرام، 0.5 گرام  
1.0 گرام انجکشن

### COMPOSITION:

#### INCETAX 1.0gm INJECTION

Each Vial contains:  
Cefotaxime Sodium Equivalent to  
Cefotaxime...USP.....1.0gram

#### INCETAX 0.5gm INJECTION

Each Vial contains:  
Cefotaxime Sodium Equivalent to  
Cefotaxime...USP.....500mg

#### INCETAX 0.25gm INJECTION

Each Vial contains:  
Cefotaxime Sodium Equivalent to  
Cefotaxime...USP.....250mg

### DESCRIPTION:

Incetax (Cefotaxime Sodium) is a semisynthetic, 3rd generation cephalosporin antibiotic for parenteral administration. Incetax (Cefotaxime Sodium) is a broad-spectrum antibiotic with activity against numerous Gram-positive and Gram-negative bacteria.

### PHARMACOLOGY:

#### Pharmacodynamics:

Incetax (Cefotaxime Sodium) is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefotaxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria. Resistance to cefotaxime is primarily through hydrolysis by beta-lactamase, alteration of penicillin-binding proteins (PBPs), and decreased permeability.

#### Pharmacokinetics:

Incetax (Cefotaxime Sodium) is not appreciably absorbed from GI tract; must be administered parenterally. Following IM administration, peak serum concentrations attained within 30 minutes. Widely distributed into body tissues and fluids, including aqueous humor, bronchial secretions, sputum, middle ear effusions, bone, bile, and ascitic, pleural, and prostatic fluids. Incetax (Cefotaxime Sodium) is distributed into CSF; highest concentrations attained in those with inflamed meninges. Crosses the placenta and is distributed into milk. Plasma Protein Binding is 13–38%. Incetax (Cefotaxime Sodium) is partially metabolized in the liver to desacetylcefotaxime, which has antibacterial activity. Desacetylcefotaxime is further metabolized into inactive metabolites in the liver. Incetax (Cefotaxime Sodium) and its metabolites excreted principally in urine. In adults with normal renal function, 40–60% of a dose excreted as unchanged drug; 24% excreted as the active metabolite. Incetax (Cefotaxime Sodium) Terminal serum half-life of cefotaxime and desacetylcefotaxime is 0.9–1.7 and 1.4–1.9 hours, respectively.

### INDICATIONS:

Incetax (Cefotaxime Sodium) is indicated for the treatment of the following severe infections

- Perioperative Prophylaxis
- Septicemia
- Meningitis and other CNS Infections
- Respiratory Tract Infections
- GI Infections including Intra-abdominal Infections
- Typhoid Fever & Vibrio Infections
- Gynecologic Infections
- Genitourinary Tract Infections
- Gonorrhea and Associated Infections
- Skin and Skin Structure Infections
- Bone and Joint Infections

### DOSAGE AND ADMINISTRATION:

#### DOSAGE:

##### Dosage in Pediatric Patients:

**Dosage for Neonates IV or IM:** 50 mg/kg every 12 hours for those <1 week of age and 50 mg/kg every 8 hours for those 1–4 weeks of age.

**Dosage for Infants and Children 1 Month to 12 Years of Age IV or IM:** 50–180 mg/kg daily given in 4–6 equally divided doses in those weighing <50 kg.

The higher dosage should be used for more severe or serious infections. Children weighing >50 kg should receive the usual adult dosage.

##### Dosage in Adults Patients:

Uncomplicated Infections IV or IM 1gm every 12 hours. Moderate to Severe Infections IV or IM 1–2gm every 8 hours.

Severe or Life-threatening Infections IV 2gm every 6–8 hours.

For life-threatening infections, 2gm every 4 hours. Maximum 12gm daily can be given.

### ADMINISTRATION:

**IV Injection or Infusion:** IV route preferred in patients severe or life-threatening infections or in patients with lowered resistance resulting from debilitating conditions IV administration may be preferred when large doses are indicated.

**Re-constitution:** Reconstitute vials containing 250mg, 500mg with 5ml sterile water and 1gm with 10ml of sterile water for injection provided in pack.

**Administration:** Inject directly into a vein over a period of 3–5 minutes or slowly into the tubing of a freely flowing compatible IV solution. Do not inject IV over <3 minutes; rapid (over <1 minute) injection is associated with potentially life-threatening arrhythmias.

**IM Injection:** Inject IM deeply into a large muscle mass such as the upper outer quadrant of the gluteus maximus.

**Reconstitution:** Reconstitute vials with compatible diluent's.

### CONTRAINDICATIONS:

Known hypersensitivity to Cefotaxime or other Cephalosporins.

### WARNINGS / PRECAUTIONS

#### Warnings:

Before therapy with Incetax Injection is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefotaxime sodium, cephalosporins, penicillins, or other drugs. Treatment with anti-infectives alters normal colon flora and may permit overgrowth of Clostridium difficile leading to C. difficile infection (CDI) and C. difficile-

