

Ceftriaxone penetrates the inflamed meninges of neonates, infants and children.

The average concentration in CSF during bacterial meningitis is 17% of the plasma concentration; in aseptic meningitis it is 4%. 24 hours after I.V. injection of **Lebacef** in doses of 50-100 mg/kg bodyweight, ceftriaxone concentrations > 1.4 mg/l were measured in CSF.

In adult patients with meningitis, administration of 50 mg/kg leads within 2-24 hours to CSF concentrations several times higher than the minimum inhibitory concentrations required for the most common causative organisms of meningitis.

Metabolism: Ceftriaxone is not metabolized in the organism itself. Only following biliary excretion into the intestinal lumen does the intestinal flora transform the active ingredient into inactive metabolites.

Elimination: Plasma clearance is 10-22 ml/min. Renal clearance is 5-12 ml/min. 50-60% of ceftriaxone is excreted unchanged via the kidneys, while 40-50% is excreted unchanged in the bile. The plasma half-life in adults is about 8 hours.

Pharmacokinetics in special patient groups: In neonates, renal elimination accounts for about 70% of the dose.

In infants aged less than 8 days and in persons aged over 75 years, the average plasma half-life is approximately 2-3 times that in healthy young adults.

In patients with mild to moderate renal failure or hepatic dysfunction, the pharmacokinetics of ceftriaxone are only slightly altered. The plasma half-life is minimally increased. If kidney function alone is impaired, biliary elimination of ceftriaxone is increased, whereas if liver function alone is impaired, renal elimination is increased.

Presentation

Lebacef 0.5 g for I.M. injection:

OPAT Kit: 1 vial containing sterile powder of ceftriaxone sodium equivalent to 0.5 g of ceftriaxone, 1 solvent ampoule containing 2 ml lidocaine solution (lidocaine hydrochloride 1%), sterile syringe, 2 needles, sterile alcohol swab, adhesive bandage.

Lebacef 0.5 g for I.V. injection:

OPAT Kit: 1 vial containing sterile powder of ceftriaxone sodium equivalent to 0.5 g of ceftriaxone, 1 solvent ampoule containing 5 ml water for injection, sterile syringe, 2 needles, sterile alcohol swab, adhesive bandage.

Lebacef 0.5 g for I.M./I.V. injection:

Pack of 10 vials each containing sterile powder of ceftriaxone sodium equivalent to 0.5 g of ceftriaxone.

Lebacef 1 g for I.M. injection:

OPAT Kit: 1 vial containing sterile powder of ceftriaxone sodium equivalent to 1 g of ceftriaxone, 1 solvent ampoule containing 3.5 ml lidocaine solution (lidocaine hydrochloride 1%), sterile syringe, 2 needles, sterile alcohol swab, adhesive bandage.

Lebacef 1 g for I.V. injection:

OPAT Kit: 1 vial containing sterile powder of ceftriaxone sodium equivalent to 1 g of ceftriaxone, 1 solvent ampoule containing 10 ml water for injection, sterile syringe, 2 needles, sterile alcohol swab, adhesive bandage.

Lebacef 1 g for I.M./I.V. injection:

Pack of 10 vials each containing sterile powder of ceftriaxone sodium equivalent to 1 g of ceftriaxone.

Lebacef 2 g for I.V. infusion:

Pack of 1 or 10 vials each containing sterile powder of ceftriaxone sodium equivalent to 2 g of ceftriaxone.

Expiry date and storage conditions

See the expiry date printed on the outer carton.

This date refers to the product correctly stored in unopened package.

Beware not to use **Lebacef** after this date.

Store below 30°C. Protect from light and heat.

Keep all medicines out of reach of children.

Manufactured by: Mitim S.R.L.

Brescia, Italy

For: ARWAN Pharmaceutical Industries Lebanon s.a.l.

Jadra, Lebanon

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.