**Patient Information Leaflet**

**CETAFOR® 2000 IV**

Ceftriaxone 2000 mg, Powder for solution for injection/ infusion

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you. If you have any further questions or if you get any side effects not listed in this leaflet, talk to your doctor, pharmacist or healthcare professional. Do not pass this medicine on to others.**

**1. What Cetafor® 2000 IV is and what it is used for**

Cetafor® is an antibiotic used in adults and children (including new-borns). It works by killing the bacteria that cause infections. It belongs to the class of “cephalosporins”. Cetafor®2000 IV is used to treat infections of: • the brain (meningitis) • the lungs • the middle ear • the abdomen and abdominal wall (peritonitis) • the urinary tract and kidneys • the bones and joints • the skin or soft tissues • the blood • the heart. It may also be prescribed for: • treating specific sexually transmitted infections (gonorrhoea and syphilis) • treating patients who have a low white blood cell count (neutropoenia) and fever due to a bacterial infection • treating chest infections in adults with chronic bronchitis. • treating Lyme disease (transmitted by tick bites) in adults and children, including new-borns, from 15 days of age • prevent infections during surgery.

**2. What you need to know before you use Cetafor®2000 IV**

**You must not receive Cetafor® if:** • You are allergic to ceftriaxone • You have had a sudden or severe allergic reaction to penicillin or any other similar antibiotic (cephalosporins, carbapenems or monobactams).

Signs of allergy include sudden swelling of the throat or face – likely to cause difficulty breathing or swallowing, sudden swelling of the hands, feet and ankles, as well as fast-developing, severe skin rash.

**Cetafor® must not be given to babies if:** • the baby is premature • is a new-born (up to 28 days of age) and has specific blood problems or jaundice (yellowing of the skin or the whites of the eye)

**Cetafor® cannot be given** when you are receiving an intravenous product containing calcium.

**Warnings and precautions:** Talk to your doctor, pharmacist or nurse before using Cetafor® if: • you have recently received – or are about to receive – a product that contains calcium. • you have recently had diarrhoea after taking antibiotics, or had any digestive tract disorders, in particular colitis (inflammation of the colon). • you have any liver or kidney problems. • you have gallstones or kidney stones. • you have any other disease, such as haemolytic anaemia (a lowering of the number of red blood cells, making the skin light yellow and causing a feeling of weakness or dyspnoea). • you are on a low-sodium diet. • you have, or have had, any combination of the following symptoms: skin rash, redness, blisters on the lips, eyes and mouth, peeling of the skin, high fever, flu-like symptoms, increased liver enzymes in your blood tests and an increased count of a certain type of white blood cells (eosinophilia), and swelling of the lymph nodes (signs of severe skin reactions).

**Children:** Talk to your doctor, pharmacist or nurse before your child is given Cetafor® if: • he/she has recently received – or is about to receive – a product that contains calcium through an intravenous injection.

**Other medicines and Cetafor®** Tell your doctor or pharmacist if you are taking, or have recently taken, an antibiotic of the aminosides family, or chloramphenicol.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Your doctor will consider the possible benefits of Cetafor® in order to treat you, as well as the risk it may involve for your baby.

**Driving and using machines**

Cetafor® can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you develop any such symptoms.

**3. How to use Cetafor® 2000 IV**

Cetafor® is administered by a doctor or a nurse. It may be either administered through an intravenous infusion, or directly injected into a vein or muscle. Cetafor® is dosed by the doctor, pharmacist or nurse and must never be mixed with, or administered at the same time as, an injection containing calcium.

**Usual posology:** Your doctor will decide which dose of Cetafor® is best for you. The dose will depend on •the severity and type of infection you have• on whether or not you are taking any other antibiotics• on your weight and age • on how your kidneys and liver are working. •The length of time for which you will receive Cetafor® will depend on the type of infection you have. **Adults, elderly people and children aged 12 years or more, with a body weight of 50kg or more:** • 1000 mg to 2000 mg, once a day, depending on the severity and type of infection. If you have a severe infection, your doctor will prescribe a higher dose (which may be up to 4 grams per day). If the daily dose you are taking is over 2000 mg, your treatment may be administered either as a single dose or as two daily doses. **New-borns, infants and children aged 15 days to 12 years, with a body weight of less than 50kg:** • 50 to 80mg of ceftriaxone per kilogramme of the child’s body weight, once a day, depending on the severity and type of infection. If you have a severe infection, your doctor will prescribe a higher dose which may be up to 100mg per kilogramme of body weight, for a maximum dose of 4 grams per day. • Children weighing 50kg or more will receive the same dose as adults. **New-borns (aged 0 to 14 days)** • 20 to 50mg of ceftriaxone per kilogramme of the child’s body weight, once a day, depending on the severity and type of infection. • The maximum daily dose should not exceed 50mg per kilogramme of the child’s body weight. **Patients with liver and kidney problems** • You may be prescribed a dosage that is different from the usual posology. Depending on how severe your liver and kidney problems are, your doctor will decide what dose of Cetafor®(ceftriaxone) is best for you and will closely monitor your health condition.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. **You must tell your doctor immediately if you have:** • Sudden swelling of the face, throat, lips or mouth, likely to cause difficulty breathing or swallowing, or sudden swelling of the hands, feet and ankles (these symptoms may be signs or a severe allergic reaction). • Fast-developing, severe skin rash, with blisters or peeling of the skin, and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis). • A combination of any of the following symptoms: extensive skin rash, high body temperature, fever, high liver enzymes, blood abnormalities (eosinophilia), hypertrophy of the lymph nodes and other organs (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Jarisch-Herxheimer reaction) • Inflammation of the large intestine (pseudomembranous colitis) may occur, particularly after prolonged antibiotic therapy. Signs include diarrhoea, generally blood and mucus, stomach pain and fever. Pseudomembranous colitis can vary from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who have diarrhoea during or after ceftriaxone administration. Discontinuation of the ceftriaxone treatment and administration of a specific treatment for *Clostridium difficile* should be considered. Peristalsis-inhibiting medicines should not be administered. • Abnormalities in the white or red blood cells, blood coagulation and other blood tests are common (up to 1 person in 10) to uncommon (may affect up to 1 person in 100). **If you get any side effects not listed in this leaflet, talk to your doctor, pharmacist or healthcare professional.**

**5. How to store Cetafor®2000 IV**

Keep out of the reach and sight of children. StoreCetafor®2000 IV below 30°C, in the original package, protected from light. Do not use after the expiry date, stated on the packaging (Exp.).The expiry date refers to the last day of that month.

**6. Contents of the vial and further information**

**The vial Cetafor® 2000 IV contains** ceftriaxone sodium equivalent to 2000 mg ceftriaxone, a sterile white to pale yellow or cream coloured crystalline powder. •contains approximately 166 mg (7.2 mmol) of sodium.

**Cetafor® 2000 IV is** a prescription medicine**. Manufacturer:** Venus Remedies Ltd – Unit II, Hill Top Industrial Estate, Jharmajri, Phase I (Extn), Bhatoli Kalan, Baddi, Dist. Solan (Himachal Pradesh), 173205 India. **Registration/License holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland. **Last revision date:** October 2019.

**7. The following information is intended for healthcare professionals only: Method and route of administration of Cetafor® 2000 IV, powder for solution for injection/ infusion**

Cetafor® may be administered as an intravenous bolus, by intravenous infusion or by intramuscular injection, after reconstitution of the solution according to the directions provided below. Ceftriaxone should not be mixed with any other substance in the same syringe. The presentation Ceftafor® 2000 IV is intended for intravenous use by infusion.

**Do not use any diluents containing calcium**, such as Ringer’s or Hartmann’s solution, to reconstitute Cetafor®. This may cause particle formation.

The colour of the solution varies from a pale yellow to an amber coloured solution, depending on storage condition, concentration of the diluent and of the type of diluent used. As a general rule, reconstituted solutions should be used immediately. Reconstituted solutions should be visually inspected. Only clear solutions not containing any visible particles may be used. The reconstituted product is for single use only and any unused solution should be eliminated.

*Intravenous infusion:* Cetafor® 2000 IV is dissolved in 40ml of one of the following calcium-free infusion fluids: sodium chloride 0.9%, sodium chloride 0.45% + dextrose 2.5%, dextrose 5%, dextrose 10%, dextran 6% in dextrose 5%, hydroxyethyl-starch 6-10%, water for injections. The infusion should be administered over at least 30 minutes.

When adding 40ml of water for injections, the final concentration of the reconstituted solution is 48.34 mg/ml.

In neonates, intravenous doses should be given over 60 minutes to reduce potential risk of bilirubin encephalopathy.

**Mixability**• **Ceftriaxone should not be mixed with, or administered at the same time as, any solutions containing calcium.** •Based on literature reports, ceftriaxone is incompatible with amsacrine, vancomycin, fluconazole, aminoglycosides and labetalol.