

**PATIENT INFORMATION LEAFLET**

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **Ceftriaxone (as sodium) 500mg Powder for Injection \***

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

1. What Ceftriaxone Powder for Injection is and what it is used for.
2. What you need to know before you are given Ceftriaxone Powder for Injection.
3. How Ceftriaxone Powder for Injection is given.
4. Possible side effects.
5. How to store Ceftriaxone Powder for Injection.
6. Contents of the pack and other information.

#### **1. WHAT CEFTRIAZONE POWDER FOR INJECTION IS AND WHAT IT IS USED FOR**

Ceftriaxone belongs to a group of antibiotics called cephalosporins. Antibiotics work by killing bacteria (bugs) which cause infections.

In patients with Human Immunodeficiency Virus (HIV)/AIDS, Ceftriaxone Powder for Injection and Infusion can be used to treat the following infections

- the brain (meningitis)
- the lungs.
- the abdomen and abdominal wall (peritonitis).
- the urinary tract and kidneys.
- bones and joints.
- the skin or soft tissues.
- the blood.
- the heart.

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1 Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea and syphilis).
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis.
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age.
- to prevent infections during surgery.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CEFTRIAZONE POWDER FOR INJECTION**

**You must not be given Ceftriazone Powder for Injection if:**

- you are hypersensitive (allergic) to ceftriazone or any of the other ingredients of this product (see section 6. What Ceftriazone Powder for Injection contains),
- you have had a sudden or severe allergic reaction to penicillin or similar antibiotic medicines ( such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly
- you are allergic to lidocaine and you are to be given Ceftriazone Powder for Injection as an injection into a muscle.

**Ceftriazone Powder for Injection must not be given to babies if:**

- The baby is premature.
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.

**Warnings and precautions:**

Talk to your healthcare provider before you are given Ceftriazone Powder for Injection if:

- You have recently received or are about to receive products that contain calcium.
- You have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- You have liver or kidney problems.
- You have gall stones or kidney stones
- You have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness).
- You are on a low sodium diet.

**If you need a blood or urine test**

If you are given Ceftriazone Powder for Injection for a long time, you may need to have regular blood tests. Ceftriazone Powder for Injection can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have been given Ceftriazone Powder for Injection.

### **Children**

Talk to your healthcare provider before your child is administered Ceftriaxone Powder for Injection if:

- Your child has recently been given or is to be given a product that contains calcium into their vein.

### **Other medicines and Ceftriaxone Powder for Injection**

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines.

In particular, tell your healthcare provider if you are taking any of the following medicines:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before taking this medicine.

The healthcare provider will consider the benefit of treating you with Ceftriaxone Powder for Injection against the risk to your baby.

### **Driving and using machines**

Ceftriaxone Powder for Injection can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your healthcare provider if you experience these symptoms.

## **3. HOW CEFTRIAZONE POWDER FOR INJECTION IS GIVEN**

Ceftriaxone Powder for Injection is usually given by a healthcare provider. It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle. Ceftriaxone Powder for Injection is made up by the healthcare provider and will not be mixed with or given to you at the same time as calcium-containing injections.

### **The usual dose**

Your healthcare provider will decide the correct dose of Ceftriaxone Powder for Injection for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given Ceftriaxone Powder for Injection depends on what sort of infection you have.

### **Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):**

- 1 to 2 g once a day depending on the severity and type of infection. If you have a severe infection, your healthcare provider will give you a higher dose (up to 4 g once a day). If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.

**Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:**

- 50-80 mg Ceftriaxone Powder for Injection for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your healthcare provider will give you a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
- Children with a body weight of 50 kg or more should be given the usual adult dose.

**Newborn babies (0-14 days)**

- 20 – 50 mg Ceftriaxone Powder for Injection for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

**People with liver and kidney problems**

You may be given a different dose to the usual dose. Your healthcare provider will decide how much Ceftriaxone Powder for Injection you will need and will check you closely depending on the severity of the liver and kidney disease.

**If you are given more Ceftriaxone Powder for Injection than you should**

If you accidentally receive more than your prescribed dose, contact your healthcare provider or nearest hospital straight away.

**If you forget to use Ceftriaxone Powder for Injection**

If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose.

**If you stop using Ceftriaxone Powder for Injection**

Do not stop taking Ceftriaxone Powder for Injection unless your healthcare provider tells you to. If you have any further questions on the use of this medicine, ask your healthcare provider.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ceftriaxone Powder for Injection can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Severe allergic reactions (not known, frequency cannot be estimated from the available data)**

If you have a severe allergic reaction, tell your healthcare provider straight away.

The signs may include:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.

**Severe skin rashes (not known, frequency cannot be estimated from the available data)**

If you get a severe skin rash, tell your healthcare provider straight away.

- The signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth.

Other possible side effects:

**Common (may affect up to 1 in 10 people)**

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

**Uncommon (may affect up to 1 in 100 people)**

- Fungal infections (for example, thrush).
- A decrease in the number of white blood cells (granulocytopenia).
- Reduction in number of red blood cells (anaemia).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Pain or a burning feeling along the vein where Ceftriaxone Powder for Injection has been given. Pain where the injection was given.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).

**Rare (may affect up to 1 in 1,000 people)**

- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty in breathing (bronchospasm).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Oedema (fluid build-up).
- Shivering.

**Not known (Frequency cannot be estimated from the available data)**

- A secondary infection that may not respond to the antibiotic previously prescribed
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.
- Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).
- Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.

- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal build up of the sugar galactose).
- Ceftriaxone Powder for Injection may interfere with some types of blood glucose tests - please check with your healthcare provider.

### **Reporting of side effects**

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE CEFTRIAZONE POWDER FOR INJECTION**

Your health care provider is responsible for storing Ceftriaxone Powder for Injection. They are also responsible for disposing of any unused Ceftriaxone Powder for Injection correctly.

Do not store above 25°C. Protect from light.

Keep this medicine out of the sight and reach of children.

Do not use Ceftriaxone Powder for Injection after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Ceftriaxone Powder for Injection contains**

Each vial contains 500mg of the active substance ceftriaxone.

### **What Ceftriaxone Powder for Injection looks like and contents of the pack**

Ceftriaxone Powder for Injection is provided as a sterile white or yellowish crystalline powder in a Type II glass vial with grey bromobutyl stopper then capsulated with aluminium pilfer-proof cap.

Ceftriaxone Powder for Injection is made into a solution by adding sterile liquid to the vial. The correct dose is then taken out of the vial. It can be given either as an injection or added to a bag of infusion solution which is given through a small tube into one of your veins.

Ceftriaxone Powder for injection is supplied in packs of 1 vial.

### **Supplier and Manufacturer**

Egyptian International Pharmaceutical Industries Co. (EIPICO)  
Tenth of Ramadan City- Industrial Area B1- Egypt  
P.O. Box: 149 Tenth of Ramadan  
Telephone: 02-2-015 361 663  
Fax: 02-2-015 364 377

**For any information about this medicinal product, please contact the supplier.**

**This leaflet was last approved in November 2016.**

Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<http://who.int/prequal/>