

## **PATIENT INFORMATION LEAFLET (PIL)**

### **SANTRIAX 1000** (Ceftriaxone for Injection USP 1000 mg)

**Read all of this leaflet carefully before you are given 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 doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

This medicine will be referred to as Ceftriaxone Injection in this leaflet.

#### **What is in this leaflet?**

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

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

Ceftriaxone for Injection is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called Cephalosporins.

SANTRIAX 1000 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
- Bones and joints
- The skin or soft tissues

- The blood
- The heart
- 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 FOR INJECTION**

### **You must not be given CEFTRIAZONE FOR INJECTION if:**

- You are allergic to ceftriazone or any of the other ingredients of this medicine
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (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 as an injection into a muscle.

### **CEFTRIAZONE 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 whites of the eyes) or is about to be given a product that contains calcium into their vein

### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before you are given Ceftriazone 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 hemolytic anemia (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 CEFTRIAXONE FOR INJECTION for a long time, you may need to have regular blood tests. CEFTRIAXONE 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 Ceftriaxone Injection

#### **Children**

Talk to your doctor or pharmacist or nurse before your child is administered ceftriaxone if:

- He/She has recently been given or is to be given a product that contains calcium into their vein

#### **Other medicines and CEFTRIAXONE FOR INJECTION**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist 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 and breast-feeding and fertility**

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 taking this medicine. The doctor will consider the benefit of treating you with Ceftriaxone Injection against the risk to your baby.

#### **Driving and using machines**

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

### **3. HOW CEFTRIAXONE FOR INJECTION IS GIVEN**

SANTRIAX 1000 is usually given by a doctor or nurse. It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle. Ceftriaxone Injection is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

#### **The usual dose**

Your doctor will decide the correct dose of SANTRIAX 1000 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 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 doctor 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

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

- 50-80 mg Ceftriaxone 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 doctor 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.

The medicinal product as such is not intended for immediate use and it has to be reconstituted with diluent before administration.

Concentrations for the intravenous injection: 100 mg/ml,

Concentrations for the intravenous infusion: 50 mg/ml

Reconstitution: From the calculated dose, determine the appropriate number of vials to be used.

For the intravenous or intramuscular injection, add the recommended volume of reconstitution solution and shake well until the contents of the vial have dissolved completely.

For the intravenous infusion, add 15 ml of reconstitution solution and shake well until the contents of the vial have dissolved completely.

Draw up this 15 ml of reconstituted solution and add it to 25 ml of reconstitution fluid in an infusion bag or add 25 ml of reconstitution fluid to the vial to prepare the patient dose (making a total volume of 40 ml reconstitution fluid).

The solution should be given by intravenous infusion.

**The following information is intended for medical or healthcare professionals only:**

**Instructions for reconstitution**

**New born babies (0-14 days)**

- 20 – 50 mg ceftriaxone 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 doctor will decide how much Ceftriaxone Injection you will need and will check you closely depending on the severity of the liver and kidney disease.

**If you are given more SANTRIAX 1000 than you should**

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

**If you forget to use SANTRIAX 1000**

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 SANTRIAX 1000**

Do not stop taking **SANTRIAX 1000** unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine 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 a doctor 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 a doctor 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 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 buildup of the sugar galactose)
- Ceftriaxone Injection may interfere with some types of blood glucose tests - please check with your doctor

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## **5. HOW TO STORE SANTRIAX 1000**

### **Keep out of reach and sight of children**

Do not use **SANTRIAX 1000** after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

Store the unopened vial below 30°C.

Once the powder has been dissolved; the solution should be used immediately. If the solution is cloudy, it should **not** be used. Any unused solution should be discarded.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

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

The active substance in **SANTRIAX 1000** is Ceftriaxone Sodium.

**What SANTRIAX 1000 looks like and the contents of the pack** Ceftriaxone for Injection contains a white to yellowish orange crystalline powder. It is supplied in 1g vial.

**Marketing Authorisation Holder:**

**BLISS GVS PHARMA LTD.**

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