

## **C-Tri XP Injection**

Ceftriaxone / Tazobactam

**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 doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

1. What C-Tri XP is and what it is used for
2. What you need to know before you take C-Tri XP
3. How to take C-Tri XP
4. Possible side effects
5. How to store C-Tri XP
6. Contents of the pack and other information

### **1. What C-Tri XP is and what it is used for**

C-Tri XP is a medicine used to treat a range of bacterial infections. It contains two active substances:

- Ceftriaxone, an antibiotic that belongs to the group of “cephalosporins” and which can kill certain bacteria that can cause infection;
- Tazobactam, which blocks the action of certain enzymes called beta-lactamases. These enzymes make bacteria resistant to Ceftriaxone by breaking down the antibiotic before it can act. By blocking their action, Tazobactam makes Ceftriaxone more effective at killing bacteria.

C-Tri XP can be used to treat infections of the:

- ✓ Blood (septicaemia)
- ✓ Skin and flesh immediately under the skin
- ✓ Bones and joints
- ✓ Brain (meningitis)
- ✓ Abdomen
- ✓ Urinary tract
- ✓ Respiratory tract
- ✓ Pneumonia
- ✓ Some sexually transmitted infections (gonorrhoea)

It can also be used to prevent and treat infections following surgical operations.

### **2. What you need to know before you take C-Tri XP**

**Do not take C-Tri XP**

- if you are allergic to Ceftriaxone, tazobactam or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines known as “cephalosporins”.
- if you have had a severe allergic reaction (e.g., severe skin peeling; swelling of the face, hands, feet, lips, tongue or throat; or difficulty swallowing or breathing) to certain other antibiotics (e.g., penicillins or carbapenems).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking C-Tri XP if you know you are, or have previously been allergic to cephalosporins, penicillins or other antibiotics.

Talk to your doctor or pharmacist if you develop diarrhoea while taking C-Tri XP.

Infections caused by bacteria that are not sensitive to C-Tri XP or caused by a fungus can occur during or following treatment with C-Tri XP. Tell your doctor if you think you may have another infection.

Treatment with C-Tri XP sometimes causes production of antibodies that react with your red blood cells. If you are told that you have an abnormal blood test (called Coombs test) tell your doctor that you are having or have recently had C-Tri XP.

**Other medicines and C-Tri XP**

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

Some medicines may interact with Ceftriaxone and tazobactam. These include:

- Probenecid (a medicine for gout).
- Another antibiotic e.g. chloramphenicol or aminoglycoside antibiotics.
- the contraceptive pill (in which case you will need to take extra contraceptive precautions such as using a condom).

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will advise if you should receive C-Tri XP during pregnancy.

If you are breast-feeding, your doctor will advise you on whether you should stop breast-feeding or stop or avoid C-Tri XP therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for you.

**3. How to take C-Tri XP**

Your doctor or other healthcare professional will give you this medicine. They will inject this medicine directly into a vein (intravenous) or muscle (intramuscular). Your doctor will decide how much you need and how often the injections should be given.

The usual doses are given below but doctors may prescribe different doses depending on the severity and type of your infection, your weight, your age and how well your kidneys are working.

**Adults**

The dose depends on the type of infection that you have, where the infection is in your body and how serious the infection is. Your doctor will decide on the dose that you need.

The usual adult daily dose is 1 to 2 grams given once in a day (or in equally divided doses twice a day) depending on the type and severity of infection.

C-Tri XP Injection therapy should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4 to 14 days; in complicated infections, longer therapy may be required. When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least 10 days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function.

#### Pediatric patients

For the treatment of skin infections, the recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 grams.

For the treatment of serious infections other than meningitis, the recommended total daily dose is 50 to 75 mg/kg, given in divided doses every 12 hours. The total daily dose should not exceed 2 grams.

In the treatment of meningitis, it is recommended that the initial therapeutic dose be 100 mg/kg (not to exceed 4 grams). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 grams daily) is recommended. The daily dose may be administered once a day (or in equally divided doses every 12 hours). The usual duration of therapy is 7 to 14 days.

#### **If you take more C-Tri XP than you should**

As this product is given by a doctor or other healthcare professional, it is very unlikely that you will be given too much C-Tri XP. However, if you have any concerns you should let your doctor, nurse or pharmacist know immediately.

#### **If you stop taking C-Tri XP**

If you think you have not been given a dose of C-Tri XP, tell your doctor or other healthcare professional immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **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:

Treatment with ceftriaxone, particularly in elderly patients with serious kidney or nervous system problems may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.

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

If you get a severe skin reaction, 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 (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting C-Tri treatment for infections with spirochete such as Lyme disease.

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 or genital fungal infections).
- 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 C-Tri has been given. Blisters, deep redness or rash, burned areas, pain, irritation, itching at the injection site.
- 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 and/or liver which may cause pain, nausea, vomiting, yellowing of the skin, itching, unusually dark urine and clay coloured stools.

- 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).

C-Tri XP 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab "Safety Reporting" located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine

### **5. How to store C-Tri XP**

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

Do not use this medicine after the expiry date which is printed on the label and carton". The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from light and moisture.

### **6. Contents of the pack and other information**

#### **What C-Tri XP looks like and contents of the pack**

#### **What C-Tri XP injection contains:**

*C-Tri XP Kid 125 mg*

Each vial contains:

Ceftriaxone Sodium equivalent to Ceftriaxone 125 mg

Tazobactam Sodium equivalent to Tazobactam 15.625 mg

*C-Tri XP 250 mg*

Each vial contains:

Ceftriaxone Sodium equivalent to Ceftriaxone 250 mg

Tazobactam Sodium equivalent to Tazobactam 31.25 mg

*C-Tri XP 500 mg*

Each vial contains:

Ceftriaxone Sodium equivalent to Ceftriaxone 500 mg

Tazobactam Sodium equivalent to Tazobactam 62.5 mg

*C-Tri XP 1 g*

Each vial contains:

Ceftriaxone Sodium equivalent to Ceftriaxone 1.0 g

Tazobactam Sodium equivalent to Tazobactam 125 mg

#### **Packing**

C-Tri XP Kid 125 mg: A vial of 140.625 mg with SWFI 5 ml

C-Tri XP 250 mg: A vial of 281.25 mg with SWFI 5 ml

C-Tri XP 500 mg: A vial of 562.5 mg with SWFI 5 ml

C-Tri XP 1 g: A vial of 1.125 g with SWFI 10 ml

**Marketing Authorisation Holder**

Zuventus Healthcare Limited  
Zuventus House, Plot Y2, CTS No.: 358/A2,  
Near Nahur Railway Station,  
Nahur (W), Mumbai, 400078 Maharashtra, India

**This leaflet was last revised in 06/2023**