Package leaflet: Information for the Patient

C Tax-O tablets 100 mg DT/200 mg Tablets

Cefixime

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 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What C Tax-O tablets is and what it is used for

C Tax-O tablets contains a medicine called Cefixime. This belongs to a group of antibiotics called 'cephalosporins'.

C Tax-O tablets is used to treat infections caused by bacteria. These include infections of the:

- Ear
- Nose, sinuses (such as sinusitis)
- Throat (such as tonsillitis, pharyngitis)
- Chest and lungs (such as bronchitis, pneumonia)
- Urinary system (such as cystitis and kidney infections)

2. What you need to know before you are given C Tax-O tablets

Do not take C Tax-O tablets if:

- You are allergic to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine (listed in section 6).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.
- Do not take this medicine if the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking C Tax-O tablets.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before you are given C Tax-O tablets if:

- You have ever had colitis.
- You have kidney problems

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Severe skin problems such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson Syndrome (SJS), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), and Acute Generalised Exanthematous Pustulosis (AGEP) have been reported with cefixime (see section 4). If you develop severe skin reactions or any of the reactions listed in section 4, stop treatment immediately and contact your doctor or healthcare professional.

Other medicines and C Tax-O tablets

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because C Tax-O tablets can affect the way some other medicines work. Also, some medicines can affect the way C Tax-O tablets works.
- In particular, tell your doctor if you are taking the following:
- o Medicines to thin the blood such as warfarin

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 or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine can cause symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. If you experience any of these effects don't drive or use machinery.

Medical Tests

If you require any tests (such as blood or urine tests) while taking this medicine, please make sure your doctor knows that you are taking C Tax-O tablets.

3. How to take C Tax-O tablets

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

C Tax-O tablets 200 mg Tablets:

- Take this medicine by mouth.
- Swallow tablets whole with a drink of water.

C Tax-O tablets 100 mg Dispersible tablets:

• Disperse the tablet in one teaspoonful (5 ml) of previously boiled & cooled water before administration.

If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to take. The medicine should be taken for the prescribed number of days.

The recommended dose is:

Adults, Elderly and Children over 10 years or weighing more than 50kg

• 200 mg – 400 mg each day given as a single or divided dose

People with kidney problems

• Your doctor may prescribe a lower dose.

Pediatric population (6 months or older)

- The recommended dose for C Tax-O DT is 8 mg/kg/day. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.
- Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose, 200 to 400 mg daily depending on the severity of infection.

If you take more C Tax-O tablets than you should

• If you have too much of this medicine, talk to your doctor straight away.

If you forget to take C Tax-O tablets

• If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking C Tax-O tablets

Do not stop taking this medicine without talking to your doctor. You should not stop taking C
Tax-O tablets just because you feel better. This is because the infection may come back or get
worse again. 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.

Tell your doctor straight away or go to the nearest hospital casualty department if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- SJS/TEN symptoms may include blistering, peeling or bleeding on any part of the skin (including the lips, eyes, mouth, nose, genitals, hands or feet). Also, flu-like symptoms such as fever, chills or aching muscles.
- DRESS symptoms may include flu-like symptoms and a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- AGEP symptoms may include a red, scaly, widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever.
- Erythema multiforme symptoms include skin rash or skin lesions with a pink/red ring and a pale
 centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms
 or soles of your feet.
- You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine.
- You bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine.
- If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia.
- Changes in the way the kidneys are working or blood in your child's urine.
- Fits (convulsions)

A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert
or aware of things than usual, unusual muscle movements or stiffness. This may be something
called encephalopathy. This side effect is more likely if you have taken an overdose or you already
have a problem with your kidneys.

Stop taking this medicine and contact your doctor without delay if you get:

• Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick (nausea) or being sick (vomiting)
- Stomach pains, indigestion or wind
- Headaches
- Feeling dizzy
- Feeling itchy in the genital or vaginal area

Blood tests

C Tax-O tablets can cause blood clots or small changes to the way the liver and kidney work. This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine.

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 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 Tax-O tablets

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

Do not use this medicine after the expiry date which is stated on the label and blister pack after EXP. Store below 25°C.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What C Tax-O tablets contains

Each film coated C Tax-O tablets 200 mg tablet contains:

Cefixime IP (as Trihydrate) equivalent to

Cefixime (Anhydrous) 200 mg

Excipients q.s.

Colour: Titanium Dioxide IP

Each uncoated C Tax-O tablets 100 mg dispersible tablet contains:

Cefixime IP (as Trihydrate) equivalent to

Cefixime (Anhydrous) 100 mg

Excipients q.s.

Colour: Lake of Quinoline Yellow

Flavour added

Packing information:

C Tax-O tablets 100 DT: A strip of 10 tablets.

C Tax-O tablets 200: A strip of 10 tablets.

Marketing Authorisation Holder

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

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