

Package Leaflet: Information for the user

C Tax - OF

Cefixime & Ofloxacin Tablets

Read all of this leaflet carefully before your child starts 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.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

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

1. What C Tax-OF tablet is and what it is used for?

C Tax-OF tablet is a combination of two medicines: Cefixime and Ofloxacin. Cefixime belongs to a group of antibiotics called “cephalosporin”. Ofloxacin belongs to a group of medicines called “quinolone antibiotics”.

Cefixime kills bacteria by preventing them from building their cell walls, while ofloxacin kills bacteria by stopping them from making and repairing their DNA. Without a cell wall or functional DNA, the bacteria cannot survive.

C Tax-OF tablets is specifically used for typhoid fever and urinary tract infections in adults.

2. What you need to know before you take C Tax-OF Tablet?

Do not take C Tax-OF Tablet if you:

- Are allergic to cefixime, ofloxacin, cephalosporins, or quinolones. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Have a history of tendinitis (inflammation or swelling of tendons) or tendon rupture related to fluoroquinolone use.
- Have epilepsy or a history of seizures/fits.
- Are pregnant, think you may be pregnant or are planning to have a baby

- Are breastfeeding.
- If you are under the age of 18 years, or are still growing
- If you suffer from or there is a family history of glucose-6-phosphate dehydrogenase deficiency (an inherited disorder that affects the red blood cells)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking C Tax-OF tablets.

Warnings and Precautions:

Talk to your doctor or pharmacist before taking C Tax-OF tablets if any of the following apply:

- if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- if you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome or Ehlers- Danlos syndrome, Turner syndrome, Sjögren's syndrome (an inflammatory autoimmune disease) or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart))
- you have or have ever had a history of mental illness.
- you have problems with your liver or kidneys.
- you have heart disease or problems with your heartbeat
- you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart).
- have salt imbalance in the blood (especially low level of potassium or magnesium in the blood)
- have a weak heart (heart failure)
- have a history of heart attack (myocardial infarction)
- you have an illness of the nervous system called 'myasthenia gravis' (muscle weakness)
- you have diabetes or blood sugar problems, as this medication can cause low blood sugar (hypoglycemia)
- Avoid strong sunlight or artificial UV rays during and for 48 hours after treatment.

During treatment

When taking this medicine

- ✓ If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately
- ✓ If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids
- ✓ If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately

- ✓ Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of C Tax-OF therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking C Tax-OF, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- ✓ You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking C Tax-OF and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking C Tax-OF.

Other medicines and C Tax-OF Tablet:

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

- medicines or dietary supplements that contain iron (for anaemia) or zinc.
- sucralfate used for stomach ulcers.
- antacids used for indigestion that contain magnesium or aluminium.
- corticosteroids, used for treatment of inflammation and swelling or over-active immune system. These may increase the risk of you developing a tendon rupture
- painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or diclofenac, or theophylline, used to treat asthma or chronic obstructive pulmonary disease as these could make you more prone to fits if taken with C Tax-OF tablet.
- glibenclamide, a medicine to control your blood sugar, as the amount of these medicines in the blood may increase and have a greater effect.
- drugs that may affect your kidney function e.g. cimetidine (used for stomach ulcers or indigestion), probenecid (used for gout) and methotrexate (used for rheumatism) as they can increase the level of ofloxacin in the blood.
- medicines to thin your blood, e.g. warfarin.
- water tablets (diuretics) such as furosemide

This medicine should not be taken within two hours of taking iron or zinc tablets, antacids, or sucralfate, as these medicines can stop C Tax-OF tablet from working properly.

If you are due to have urine tests for porphyrin (a pigment in the blood), or for opiates (strong painkillers), tell your doctor or nurse you are taking this medicine.

Pregnancy and breast-feeding

Do not take C Tax-OF tablet if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. If you become pregnant while taking C Tax-OF tablet, stop taking the tablets and contact your doctor immediately.

Driving and using machines

Taking C Tax-OF tablet may make you feel sleepy, dizzy or could affect your eyesight. Do not drive or use machines until you know how this medicine affects you. Drinking alcohol may make these symptoms worse.

3. How to take C Tax-OF Tablet?

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

- For oral use. You should swallow these tablets whole with water. Do not chew them.
- The tablets can be taken with or without food and can be divided into equal doses.
- When taking C Tax-OF, avoid strong sunlight and do not use sun lamps or solaria as your skin may be more sensitive to light.
- If you are taking iron tablets (for anaemia), antacids (for indigestion or heartburn) or sucralfate (for stomach ulcers), it is important not to take these two hours before or after taking C Tax-OF. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.
- When taking C Tax-OF, if your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately

Dosage in Adults:

Take 1 tablet twice daily, as directed by your doctor.

Use in children and adolescents:

Children or adolescents under 18 years of age should not take these tablets.

If you take more C Tax-OF tablet:

If you take more tablets than you should you may become confused and dizzy or lose consciousness, you may have a seizure or fit, and you may feel sick. Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

If you forget to take C Tax-OF tablet:

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten tablet

If you stop taking C Tax-OF tablet:

Your doctor will tell you how long you need to take your tablets for. Do not suddenly stop taking this medicine without talking to your doctor first. If you stop, your infection may get worse again. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

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. Stop taking C Tax-OF, tell your doctor or go to your nearest hospital casualty department straight away if you have any of the following serious side effects because you may need medical attention:

With Ofloxacin:

Uncommon (may affect up to 1 in 100 people)

resistance of infection causing organisms to this treatment, (you may fail to respond to treatment)

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

- you have an allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as: - severe skin rash - swelling of the face, lips, mouth, tongue or throat (angioedema) - anaphylactic shock (sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing)
- inflammation of the bowel, which may cause severe watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature
- swelling of the tendons with the following symptoms; pain, tenderness, sometimes restricted movement (tendonitis). This can lead to tendon rupture, especially of the large tendon at the back of the ankle (Achilles tendon). The risk of this occurring is increased if you are also taking corticosteroids e.g. prednisolone
- numbness or tingling in the hands and feet or being very sensitive to touch, numbness or weakness of the arms and legs
- blurred, double or altered colour vision. If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Very rare (may affect up to 1 in 10,000 people):

- a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal or an illness resulting from the destruction of red blood cells with the following symptoms; feeling tired, faint, dizzy, being short of breath when exercising and having pale skin. These may be signs of anaemia or haemolytic anaemia.
- other blood disorders when the numbers of different types of cells in the blood may fall, which may cause fever, chills, sore throat, ulcers in the mouth and throat (leucopenia, agranulocytosis)
- fits (seizures)
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).
- narrowing, blockage or leakage of blood vessels, in exceptional cases leading to severe skin reactions and death of areas of the skin
- severe kidney problems, which may result in your kidneys stopping working. Signs may include a rash, high temperature, general aches and pains, or blood in the urine
- hearing problems or hearing loss
- liver problems, such as inflammation of the liver (hepatitis) or blockage in the bile duct, that may cause your eyes or skin to go yellow (jaundice) or you may notice the following symptoms; nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, light coloured bowel motions, dark coloured urine

With Cefixime:

- liver problems, such as inflammation of the liver (hepatitis) or blockage in the bile duct, that may cause your eyes or skin to go yellow (jaundice) or you may notice the following symptoms; nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, light coloured bowel motions, dark coloured urine
- 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
- 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.

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.

You can also report side effects directly:

Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top end of the home page.

Website link: <https://www.zuventus.co.in/drug-safety-reporting>

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

You can also report the side effect with the help of your treating physician.

5. How to store C Tax-OF tablet?

Keep this medicine out of the sight and reach of children. Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store below 25°C. Protect from light & moisture

6. Contents of the pack and other information

What C Tax-OF contains

Each film coated tablet contains:

Cefixime (as Trihydrate) IP equivalent to Anhydrous Cefixime 200 mg

Ofloxacin IP 200 mg

Excipients q.s.

Colours: Lake of Quinoline Yellow & Titanium Dioxide IP

Packaging information

A blister strip of 10 tablets.

Marketing Authorisation Holder

Zuventus Healthcare Ltd.

Zuventus House, Plot Y2, CTS No: 358/A2,

Near Nahur Railway Station,

Nahur (West), Mumbai 400 078.

This leaflet was last revised in July 2024