

Consumer Medicine Information**WARNING****Serious disabling and potentially irreversible.****Some serious side effects may be long-lasting (more than 30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.****What is in this leaflet**

This leaflet answers some common questions about C-FLOX. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking C-FLOX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What C-FLOX is used for

C-FLOX tablets are used to treat certain infections of the:

- lungs
- skin
- bones and joints
- kidney and bladder
- prostate
- bowel

C-FLOX is also used to treat inhalational anthrax (an infection caused by breathing in the spores of bacteria).

C-FLOX tablets contain the active ingredient ciprofloxacin (as hydrochloride), which is an antibiotic belonging to a group of medicines called quinolones (pronounced kwin-o-lones). These antibiotics work by killing the bacteria that are causing your infection.

C-FLOX does not work against infections caused by viruses, such as colds or the flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take C-FLOX**When you must not take it**

Do not take C-FLOX if you have an allergy to:

- ciprofloxacin
- other quinolone antibiotics including nalidixic acid, moxifloxacin, norfloxacin
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take C-FLOX if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of the spinal cord.

C-FLOX can interfere with tizanidine and can lead to undesirable side effects.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

C-FLOX is not recommended if you are pregnant. Medicines similar to C-FLOX have caused joint disease in immature animals.

Your doctor will discuss the risks and benefits of taking C-FLOX during pregnancy.

Do not take C-FLOX if you are breastfeeding.

C-FLOX passes into breast milk and may affect your baby. Your doctor will tell you whether you should take C-FLOX or temporarily stop breastfeeding while you are taking the tablets.

C-FLOX is not recommended for children under 18 years of age except for use in inhalational anthrax.

C-FLOX should be used with caution in elderly patients as they are more prone to side effects.

Tell your doctor if you have or have had any of the following medical conditions:

- epilepsy, fits, seizures or convulsions
- stroke
- kidney disease
- liver disease
- arrhythmias (fast or irregular heartbeats). C-FLOX may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
- conditions where you have taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement
- myasthenia gravis, a condition where the muscles become weak. C-FLOX can worsen symptoms of this condition
- a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)
- have or have had a mental illness
- have diabetes

If you have not told your doctor about any of the above, tell them before you start taking C-FLOX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by C-FLOX, or may affect how well it works. These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, medicines used to prevent blood clots such as warfarin and its derivatives
- phenytoin, a medicine used to treat epilepsy
- medicines used to control diabetes
- didanosine, a medicine used to treat viral infections
- ciclosporin, a medicine used to suppress the immune system following organ transplantation
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat severe rheumatoid arthritis, severe psoriasis or some types of cancer
- duloxetine, a medicine used to treat depression, anxiety and nerve pain in people with diabetes
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease or restless legs syndrome
- lidocaine, a local anaesthetic medicine used to numb pain or cause loss of sensation
- pentoxifylline, a medicine used to treat circulation disorders
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat sleep disorders

These medicines may be affected by C-FLOX, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Some medicines may interfere with the absorption of C-FLOX.

These include:

- multivitamins, mineral supplements, antacids (used for indigestion) and other medicines containing iron, zinc, magnesium, aluminium or calcium

- sucralfate, a medicine used to treat duodenal or stomach ulcers
- medicines used to treat HIV infection
- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where the stomach produces too much acid
- sevelamer, a medicine used to treat high blood levels of phosphorus in patients with kidney disease who are on dialysis
- metoclopramide, a medicine used to treat nausea and vomiting, heartburn and stomach pain

You can still take these medicines while you are taking C-FLOX. However, you must take C-FLOX at least 2 hours before or 2 hours after taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take C-FLOX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much and how often you should take C-FLOX. This will depend on the type of infection and any medical conditions you have.

The usual adult dosage for most infections is one tablet twice daily for 7 to 14 days. You may need to take your tablets for a longer period of time for some types of infection.

Elderly people and people with kidney problems may need smaller doses.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

C-FLOX tablets are usually taken twice a day.

Take your tablets at the same time each day, preferably on an empty stomach. However, C-FLOX can be taken with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

The length of treatment may vary from 1 to 28 days or longer depending on the type of infection.

Do not stop taking C-FLOX even if you are feeling better, unless advised by your doctor.

If you stop taking your medicine too soon, the infection may not clear completely or your symptoms may return.

If you forget to take it

If you forget to take C-FLOX tablets and it is:

- 6 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.

- Less than 6 hours until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much C-FLOX.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking C-FLOX

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking C-FLOX.

Tell all other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you are about to have any laboratory, blood or urine tests, tell your doctor that you are taking this medicine.

It may affect the results of some tests.

Drink plenty of water while you're taking C-FLOX.

This helps to stop crystals forming in your urine.

If you become pregnant while taking C-FLOX, tell your doctor immediately.

If you develop diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking C-FLOX.

Diarrhoea may mean that you have a serious condition affecting your bowel.

You may need urgent medical care.

Do not take any medicines for diarrhoea without checking with your doctor or pharmacist.

Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour. C-FLOX should be discontinued immediately.

Tell your doctor immediately if you develop pain, burning, tingling, numbness or weakness in any part of the body. C-FLOX should be discontinued immediately.

Things you must not do

Do not take C-FLOX to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your tablets because you are feeling better, unless your doctor told you to do so.

If you do not complete the full course prescribed by your doctor, some of the

bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear up completely or it may return.

Things to be careful of

Avoid excessive exposure to direct sunlight.

Your skin may become more prone to sunburn. If such a reaction occurs, stop taking C-FLOX immediately and tell your doctor.

Be careful driving or operating machinery until you know how C-FLOX affects you.

C-FLOX may cause dizziness in some people, especially after the first few doses. Your ability to drive and/or operate machinery may be impaired. If you drink alcohol while taking this medicine, dizziness may be worse.

C-FLOX tablets may increase the stimulatory effects of caffeine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking C-FLOX.

This medicine is generally well tolerated and helps most people with bacterial infections, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- diarrhoea

These are the more mild and common side effects of your medicine.

Tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- severe skin rashes, peeling of the skin and/or mucosal reactions
- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing
- fainting
- yellowing of the skin and eyes, also called jaundice
- severe watery or bloody diarrhoea, even if it occurs several weeks after taking your tablets
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations and psychotic reaction (even progressing to self-endangering behaviour)
- fast or irregular heartbeats
- visual disturbances (eyesight problems)
- ringing in the ear, loss of hearing
- abdominal pain/cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue
- pain, burning, tingling, numbness and/or weakness in your limbs

- hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) which may include fever, extensive skin rash, swollen lymph nodes, blood abnormalities and inflammation of internal organs like liver, lung or kidney.

The above list includes serious side effects that may require medical attention.

In isolated instance, some serious side effects may be long-lasting (more than 30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.

Photosensitivity (getting sunburnt very easily) can occasionally occur with C-FLOX. However, it is temporary and staying out of direct sunlight while taking C-FLOX will prevent this from happening.

Rarely, there can be a worsening of the symptoms of myasthenia gravis. This is a condition in which the muscles become weak and tire easily, causing drooping eyelids, double vision, difficulty in speaking and swallowing, and sometimes muscle weakness in the arms or legs.

Rarely, the Achilles tendon (extending from the calf muscle in the leg to the heel of the foot) or other tendons have been torn after C-FLOX therapy. This may occur even within the first 48 hours of treatment and up to several months after completing treatment with C-FLOX. This risk of tendon damage may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants.

Tell your doctor immediately if you feel any discomfort, pain or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar) or hypoglycaemia (low blood sugar). Symptoms of hyperglycaemia include increased thirst, appetite and urination. Symptoms of hypoglycaemia include weakness, shaking, sweating, light headedness, headache, behavioural changes, confusion, numbness/pins and needles in the lips, fingers or toes, irritability and hunger. Tell your doctor if you experience these symptoms.

If you experience any of these symptoms during treatment with C-FLOX, tell your doctor or pharmacist immediately. C-FLOX may need to be discontinued.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using C-FLOX

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store C-FLOX or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

C-FLOX is available in 3 tablet strengths:

- C-FLOX 250: white, biconvex, round, film-coated tablet marked "CF" scoreline "250" on one side and "G" on the reverse side. Packs of 14 tablets
- C-FLOX 500: white, biconvex, capsule shaped, film-coated tablet marked "CF" scoreline "500" on one side and "G" on the reverse side. Packs of 14 tablets
- C-FLOX 750: white, biconvex, capsule shaped, film-coated tablet marked "CF" scoreline "750" on one side and "G" on the reverse side. Packs of 14 tablets

Ingredients

The active ingredient in C-FLOX is ciprofloxacin (as hydrochloride).

Each tablet contains:

- C-FLOX 250 - ciprofloxacin (as hydrochloride) 250 mg
- C-FLOX 500 - ciprofloxacin (as hydrochloride) 500 mg
- C-FLOX 750 - ciprofloxacin (as hydrochloride) 750 mg

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- maize starch
- crospovidone
- pregelatinised maize starch
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide CI77891 (E171)
- polydextrose
- triacetin
- macrogol 8000

C-FLOX contains trace quantities of sulfites.

Supplier

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30 - 34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian registration numbers:

C-FLOX 250 - AUST R 195202

C-FLOX 500 - AUST R 195203

C-FLOX 750 - AUST R 195204

C-FLOX® is a Viatris company trade mark

This leaflet was prepared in October 2024.

C-FLOX _cmi\Oct24\00