

C-FLOX

contains the active ingredient ciprofloxacin (as hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about C-FLOX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking C-FLOX against the benefits expected for you.

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

Keep this leaflet with your 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 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 flu, or fungi.

Ask your doctor if you have any questions about why C-FLOX has been prescribed for you.

Your doctor may have prescribed C-FLOX for another reason.

C-FLOX is available only with a doctor's prescription.

There is no evidence that C-FLOX is addictive.

Before you take C-FLOX

When you must not take it

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

- * ciprofloxacin (eg. Ciproxin)
- * other quinolone antibiotics including nalidixic acid
- * any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not give C-FLOX to children and growing adolescents unless you are told by your doctor to do so.

Do not take C-FLOX if you are breastfeeding.

C-FLOX passes into breast milk and may affect your baby. Your doctor will advise you on what to do.

Do not take C-FLOX tablets after the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take C-FLOX if the packaging is torn, shows sign of tampering or the tablets do not look quite right.

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 are allergic to any other medicines, foods, dyes or preservatives.

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

It is not known whether this medicine is safe to use in pregnant women. Like other quinolone medicines, ciprofloxacin has been reported to cause joint disease in young animals. Your doctor will discuss the risks and benefits of taking C-FLOX during pregnancy.

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

- * epilepsy, fits, seizures or convulsions
- * brain disease
- * myasthenia gravis, a condition where there is severe muscle weakness
- * cystic fibrosis

- * liver problems
- * kidney problems.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you are elderly or have previously taken corticosteroids such as prednisolone or cortisone.

You may be at an increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes, restricted movement.

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 if you are taking any other medicines, including any that you buy 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:

- * theophylline, a medicine used to treat asthma
- * omeprazole, a medicine used to treat heartburn or stomach ulcers
- * medicines used to prevent blood clots such as warfarin
- * probenecid, a medicine used to treat gout
- * glibenclamide, a medicine used to control diabetes
- * cyclosporin, a medicine used in organ transplantation or to treat certain problems with the immune system
- * NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve symptoms of inflammation such as pain and swelling, in conditions such as arthritis
- * caffeine, found in some medicines and in drinks such as coffee, tea, cola
- * methotrexate, a medicine used to treat arthritis and some types of cancer.

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

These include:

- * medicines containing iron, magnesium, aluminium or calcium such as multivitamins and mineral supplements
- * antacids used for indigestion
- * sucralfate, a medicine used to treat duodenal or stomach ulcers
- * some medicines used in viral infections
- * sevelamer, a medicine used to treat high levels of phosphate in the blood.

Your doctor can tell you what to do if you are 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 C-FLOX.

How to take C-FLOX

Follow all directions given to you by your doctor and 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.

How much to take

The dose varies from person to person.

The usual adult dosage for most infections is one tablet twice daily for 7 to 14 days.

Your doctor will advise you on your dose and length of treatment, depending on the type of infection you have and its severity.

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

How to take it

Swallow the tablets whole with a glass of water or other fluid.

When to take it

C-FLOX tablets are usually taken twice a day.

Take your tablets at the same time each day.

C-FLOX can be taken with or without food.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do or have any questions, ask your doctor or pharmacist for help.

How long to take it

Continue taking C-FLOX until you have finished the pack or 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're feeling better after a few days, unless advised by your doctor.

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

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking C-FLOX.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking C-FLOX.

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

This helps prevent crystals forming in the urine.

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

If you get severe 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 diarrhoea medicine without checking with your doctor.

Protect your skin when you are in the sun, especially between 10 am and 3 pm.

C-FLOX may cause your skin to be much more sensitive to sunlight than it is normally. This may cause a skin rash, itching, redness or, a severe sunburn.

If outdoors, wear protective clothing and use a SPF 30+ sunscreen. If your skin does appear to be burning, stop taking C-FLOX and tell your doctor.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you need to have any blood or urine tests, tell your doctor that you are taking C-FLOX.

C-FLOX may affect the results of some tests.

Things you must not do

Do not use C-FLOX to treat any other conditions unless your doctor tells you to.

Do not give C-FLOX 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

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

C-FLOX may cause dizziness and lightheadedness in some people, especially after the first few doses. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. If you drink alcohol, dizziness or lightheadedness 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.

Ciprofloxacin (C-FLOX) is generally well tolerated and helps most people with their 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 to stop taking the tablets or have medical treatment if you get some of these side effects.

Do not be alarmed by this list of possible 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 mild and common side effects and they worry you:

- * nausea (feeling sick) or vomiting
- * mild diarrhoea
- * headache, dizziness or lightheadedness
- * mild stomach pains, heartburn
- * vaginal itching or discharge
- * bad taste.

Tell your doctor immediately if you notice any of the following:

- * agitation, restlessness
- * itching or rash
- * nausea or vomiting, with loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, dark coloured urine
- * twitching; unusual muscle stiffness causing poor control of movement
- * bloody or cloudy urine; fever; skin rash; swelling of lower feet or legs
- * worsening of myasthenia gravis symptoms, 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.

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

If any of the following happen, stop taking C-FLOX and tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- * changes in heart rhythm or fast heart beat
- * chest pain
- * fits or seizures
- * confusion, hallucinations, changes in mood
- * thought disturbances including thoughts of self-harm
- * symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- * inflamed, painful or ruptured joints or tendons, such as the Achilles tendon
- * severe watery or bloody diarrhoea, even if it occurs several weeks after taking your tablets
- * getting sunburnt easily; symptoms of sunburn include redness, itching, swelling, blistering
- * pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- * peeling or loosening of skin and/or severe blisters with bleeding of the lips, eyes, mouth, nose and genitals
- * a severe rash with skin peeling, fever, chills and aching muscles
- * bleeding or bruising more easily than normal, nose bleeds
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers
- * symptoms of hypoglycaemia (low blood sugar) such as

sweating, weakness, dizziness, trembling, headache and a fast pounding heartbeat.

The side effects listed above are very serious, and may need urgent medical attention or hospitalisation.

After finishing C-FLOX

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with C-FLOX:

- * severe abdominal cramps or stomach cramps
- * watery and severe diarrhoea, which may also be bloody
- * fever, in combination with one or both of the above.

These are rare but serious side effects.

C-FLOX can cause the harmless bacteria, which are normally present in the bowel, to multiply and produce the above symptoms. You may need urgent medical attention.

Do not take any diarrhoea medicine without first checking with your doctor.

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

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

This is not a complete list of all possible side effects.

After taking C-FLOX

Storage

Keep C-FLOX 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.

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 degrees C.

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

Do not leave C-FLOX in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking C-FLOX, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

C-FLOX tablets are available in 3 strengths:

- * C-FLOX 250: white, film-coated, round, scored tablet; marked "CIP 250" on one side and a Bayer Cross on the other side
- * C-FLOX 500: white, film-coated, oblong, scored tablet; marked "CIP 500" on one side and "BAYER" on the other side
- * C-FLOX 750: white, film-coated, oblong tablet; marked "CIP 750" on one side and "BAYER" on the other side.

Each pack contains 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:

- * colloidal silicon dioxide
- * crospovidone
- * macrogol 4000
- * maize starch
- * magnesium stearate
- * microcrystalline cellulose
- * hypromellose
- * titanium dioxide CI77891 (E171).

The tablets are gluten free.

Manufacturer

BAYER AG, Germany

Supplier

C-FLOX is supplied in Australia by:.

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian registration numbers:

C-FLOX 250 - AUST R 80524

C-FLOX 500 - AUST R 80525

C-FLOX 750 - AUST R 80505

This leaflet was prepared on
15 August 2006.