

Co-Fluampicil Capsules
250mg/250mg
PACKAGE LEAFLET: INFORMATION FOR THE USER

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.
- 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 of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET:

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

1. WHAT CO-FLUAMPICIL IS AND WHAT IT IS USED FOR

Your capsules are called Co-Fluampicil Capsules.

They are part of a group of drugs known as penicillin antibiotics.

Co-Fluampicil Capsules are used to treat a variety of severe infections where the bacterium causing the infection is not known or where more than one bacterium are involved. These include chest infections, ear, nose and throat and soft tissue infections. In hospitals, Co-Fluampicil Capsules may be used to treat respiratory tract infections, post-operative chest and wound infections and septicaemia (blood poisoning). They may also be given after childbirth or abortion, before major surgery or to patients who are taking drugs that reduce the body's resistance to infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-FLUAMPICIL

You should not take your capsules if you:

- have a history of flucloxacillin-associated jaundice/liver impairment;
- have ever had a bad reaction to any of the ingredients listed in the 'What is in your capsules' section or to other penicillin antibiotics;

Warnings and precautions

Talk to your doctor before taking Co-Fluampicil if you:

- know that you are allergic to food, cosmetics, pollen, fur and so on;
- have ever had any problems with your kidneys;
- suffer from an inherited metabolic disorder called porphyria;
- have the HIV virus, infectious mononucleosis or suffer from leukaemia.

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following:-

- are taking anticoagulants (to stop your blood clotting), other antibiotics, for example chloramphenicol, methotrexate (for psoriasis, rheumatoid arthritis or cancer), or probenecid (for gout);
- are taking the oral contraceptive pill as your antibiotic may cause the pill to be less effective;
- are taking other medicines including ones that you have bought for yourself without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

3. HOW TO TAKE CO-FLUAMPICIL

You must take your capsules as your doctor has told you to. The label will tell you how many to take and how often to take them. The number of capsules you take is called the 'dose'. The most common dose for these capsules, for adults and children over 10 years old, is one capsule four times a day.

Children under 10 years old should take Co-Fluampicilliquid.

For oral use

Swallow the capsule whole with water and take it approximately 1 hour before meals. Your doctor will decide how long you should take your capsules for. Do not stop taking them as soon as you feel better, take all the capsules your doctor has given you.

If you forget to take a dose at the right time, take it as soon as you remember. Do not take two doses together. If it is almost time to take the next dose, wait until then and then carry on as before.

If you take more Co-Fluampicil than you should

It is important not to take too many capsules.

Contact your nearest hospital Accident and Emergency department or a doctor for advice if you have swallowed too many capsules or if you think a child has accidentally swallowed any.

Take this leaflet, and any capsules that you still have to show the doctor

4. POSSIBLE SIDE EFFECTS

You may have some side effects while you are taking your capsules. These are usually mild and do not last very long..

Blood and lymphatic system disorders:

Decrease in the number of white blood cells, decrease of platelets in blood, red blood cells are destroyed and removed from the bloodstream before their normal lifespan is over have been reported rarely.

Gastrointestinal disorders :

Rarely, Co-Fluampicil Capsules can cause your bowel to become inflamed. This may cause pain and bloody diarrhoea. Skin haemorrhage and fever have also been reported.

Renal and urinary disorders

Occasionally, Co-Fluampicil capsules cause kidney inflammation or blood disorders.

Immune system disorders:

Skin rash, itching, swelling of lips, eyes or tongue reported occasionally. Red or purple discolouration on skin. Skin disease that causes lesions and redness around the lesions, stevens-Johnson syndrome, life-threatening dermatological condition that is usually induced by a reaction to medications have been reported rarely. Fever, severe pain in a joint, muscle pain

Hepatobiliary disorders:

Occasionally, Co-Fluampicil Capsules may cause liver damage. Your skin and the whites of your eyes may look slightly yellow (jaundice). This can happen up to two months after you have stopped taking your medicine,

If you notice any of these side effects or you feel unwell in any other way, you should see your doctor.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE CO-FLUAMPICIL

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

You should keep your capsules in a cool dry place.

Keep them in the pack they came in. Do not put them into another container. .

Do not use this medicine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-Fluampicil Capsules contain:

- Co-Fluampicil Capsules contain 250mg flucloxacillin as flucloxacillin sodium and 250mg ampicillin as ampicillin trihydrate (active ingredients) and
- Magnesium stearate (inactive ingredient). The capsule shell contains gelatin, titanium dioxide (E171), indigo carmine (E132) and black iron oxide (E172).

Co-Fluampicil Capsules are blue and grey with FXN/AMP on the cap and a twin triangle logo on the body.

What Co-Fluampicil Capsules look like and contents of the pack

They come in packs of 7, 14, 15, 20, 21, 28, 30, 50, 56, 60, 100, 250, SOD, 1000.

Marketing Authorisation Holder and Manufacturer

Your capsules are made by Norton Antibiotics Limited, 2-3 Zennor Road, London SW12 0PS, United Kingdom.

The marketing authorisation holder is Norton Healthcare Limited, T/A IVAX Pharmaceuticals UK Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX.

This leaflet was updated in September 2014 PL number 00530/0178