

PACKAGE LEAFLET INFORMATION FOR THE USER

Co-fluampicil 250mg/250mg Hard Capsules

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or nurse.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours

The name of your medicine is Co-fluampicil 250mg/250mg Hard Capsules. In the rest of this leaflet it is called Co-fluampicil Capsules.

In this leaflet:

1. What co-fluampicil is and what it is used for
2. Before you take Co-fluampicil Capsules
3. How to take Co-fluampicil Capsules
4. Possible side effects
5. How to store Co-fluampicil Capsules
6. Further information

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

Co-fluampicil Capsules contain two active ingredients, ampicillin and flucloxacillin which together are known as co-fluampicil. Co-fluampicil Capsules are an antibiotic medicine. They belong to the penicillin group of antibiotics and work by killing bacteria that cause infections.

Co-fluampicil Capsules are used to treat a wide range of infections caused by bacteria. These infections may affect the chest, ear, nose, throat, skin and soft tissues.

In hospital this medicine may also be used to prevent and treat infections:

- which occur after surgery
- in patients receiving treatment which affects the immune system of the blood (septicaemia)
- associated with difficulties in childbirth (septic abortion (abortion complicated by fever, often leading to sepsis) and puerperal fever (an infection of the membrane of the uterus following childbirth or abortion).

2. BEFORE YOU TAKE CO-FLUAMPICIL CAPSULES

Do not take Co-fluampicil Capsules if you:

- know that you are allergic to penicillin, cephalosporins, any other antibiotic or any of the ingredients contained in Co-fluampicil Capsules (see 'What Co-fluampicil Capsules contain' in section 6)
- have ever had a skin rash or swelling of the face or neck when taking an antibiotic
- have ever had a serious complaint, such as liver problems, when taking an antibiotic.

If any of the above statements apply to you, you should not be given Co-Fluampicil Capsules.

Speak to your doctor before taking Co-fluampicil Capsules if you:

- are being treated for kidney or liver problems
- have glandular fever
- are having blood tests because your medicine sometimes causes short term changes in blood cell counts.
- have syphilis or leptospirosis

Additional monitoring of kidney and liver function is recommended for patients on prolonged treatment e.g. osteomyelitis (bone infection) or endocarditis (infection of the muscle around the heart).

If any of the above apply your doctor may decide to change the dose of Co-fluampicil Capsules or prescribe a different medicine.

Taking other medicines

Taking another medicine while you are taking Co-fluampicil Capsules can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those you may have bought yourself without a prescription.

Tell your doctor if you are using the following medicines (or any other medicines):

- a contraceptive pill as you will need to take extra precautions such as use of a condom
- probenecid and allopurinol, used in the treatment of gout
- or if you are being treated with any other antibiotic (e.g. penicillins-including ampicillin, or bacteriostatic agents like chloramphenicol, erythromycins or tetracyclines)
- methotrexate, used to treat cancer, autoimmune diseases.

If you are required to have a urine test, please inform your doctor you are taking Co-fluampicil. False positive results can occur with certain tests for sugar in the urine (e.g. the Fehling's test), tests that look for antibodies, (e.g. Coomb's test) or test for protein in the urine (e.g. Copper Sulphate test) whilst taking Co-fluampicil.

If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

Pregnancy and breast-feeding

You should let your doctor know if you are pregnant, think you might be pregnant or are breast-feeding before taking this medicine. Your doctor will decide if this medicine is suitable for you.

Important information about the sodium content of Co-fluampicil Capsules

This medicinal product contains 13.0mg of sodium per capsule. This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e essentially 'sodium free'.

3. HOW TO TAKE CO-FLUAMPICIL CAPSULES

Always take Co-fluampicil Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The dose of Co-fluampicil your doctor prescribes and the length of time for which you will have to take it, will depend on your infection.
- The usual dose of Co-fluampicil Capsules for the elderly, adults and children over 10 years of age is one capsule four times a day. If your infection is severe, your doctor may double this dose to two capsules four times a day.
- For children under 10 years of age Co-fluampicil Syrup should be used.
- Try to take your capsules as part of your daily routine and space the doses as evenly as possible through the day – for example before meal times and at bedtime. You do not need to take a dose in the middle of the night unless your doctor has told you to do so.
- Co-fluampicil Capsules should be swallowed whole with a glass of water half an hour to one hour before food. If this medicine is taken with food it may not work as well as it should.

If you take more Co-fluampicil Capsules than you should

If you take too many Co-fluampicil Capsules contact your doctor or hospital casualty department immediately. Take this leaflet and any remaining capsules with you. Symptoms of an overdose include feeling sick, being sick and diarrhoea.

If you miss a dose of Co-fluampicil Capsules

If you forget to take a dose at the right time, take it as soon as you remember. Then go on as before. But don't take the next dose too soon. Always try to keep the doses evenly spaced and do not take two doses within one hour or so of each other.

If you stop taking Co-fluampicil Capsules

Keep taking your capsules until the prescribed course is finished. Do not stop just because you feel better. If you stop too soon, the infection may start up again. If you feel unwell at the end of your course of treatment, tell your doctor.

4. POSSIBLE SIDE EFFECTS

Like many medicines Co-fluampicil Capsules may cause side effects in some patients, particularly when treatment is first started, although not everybody gets them.

Stop taking Co-fluampicil Capsules and see your doctor **immediately** if you:

- get severe diarrhoea with bleeding or stomach pain
- notice your urine becoming darker or your faeces becoming paler
- notice your skin or the whites of your eyes turning yellow
- notice red or purple discolourations on the skin
- notice that your face is swollen and you have breathing problems
- start to itch or get a rash
- notice blistering of the skin, mouth, eyes or genitals
- notice increased bleeding/bruising, pale skin or weakness (due to changes in the levels of certain blood cells)
- develop nephritis (inflammation of the kidneys that can cause swollen ankles or high blood pressure)
- develop a fever
- have porphyria (rare hereditary disease where the blood pigment haemoglobin is abnormally metabolised) as there is a potential of acute attacks
- notice red lumps on both lower legs
- develop pain in your joints
- notice your lymph nodes become enlarged
- notice that you are tired and have shortness of breath
- have blood in your urine
- develop muscle weakness and fatigue
- start to hallucinate

Frequent side effects which are usually mild include

- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea

Other side effects

- coma (if you are on very high doses)
- difficulty breathing

If you have Syphilis:

Patients who have syphilis have occasionally suffered from a type of reaction (Jarisch-Herxheimer reaction) shortly after treatment, with fever, chills, headache and reactions at the site of lesions.

Some of these reactions can be delayed for several weeks after finishing the treatment.

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 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 CAPSULES

Keep out of the sight and reach of children

Do not take the medicine after the expiry date printed on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original container in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Co-fluampicil Capsules contain

Co-fluampicil Capsules contain two active ingredients, ampicillin and flucloxacillin which together are known as co-fluampicil. Each capsule contains 250 mg ampicillin as ampicillin trihydrate and 250 mg of flucloxacillin as flucloxacillin sodium.

Your medicine also contains inactive ingredients. These are quinoline yellow (E104), patent blue V (E131), iron oxides (E172), titanium dioxide (E171), magnesium stearate (E572) and gelatin.

Contents of the pack

Co-fluampicil Capsules are available in two pack sizes, 28 and 100. The most common pack of capsules you are likely to receive is 28 capsules, but this may vary depending on the length of treatment your doctor has prescribed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: Laboratorio Reig Jofre, S.A. c/Jarama, s/n. (Polígono Industrial) 45007 Toledo, Spain.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product Name	Reference Number
Co-fluampicil 250/250mg Hard Capsules	PL 29831/0052

This is a service provided by the Royal National Institute of Blind People.

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 **WOCKHARDT**

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