

Co-Amoxiclav 500/125 mg Tablets

(Amoxicillin and Clavulanic acid)

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Co-Amoxiclav is and what it is used for
2. Before you take Co-Amoxiclav
3. How to take Co-Amoxiclav
4. Possible side effects
5. How to store Co-Amoxiclav
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1 What Co-Amoxiclav is and what it is used for

Co-amoxiclav is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Co-amoxiclav is used in adults and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

2 Before you take Co-Amoxiclav

Do NOT take Co-amoxiclav:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Co-amoxiclav (listed in section 6)
- if you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take Co-amoxiclav if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-amoxiclav.

Take special care with Co-amoxiclav

Talk to your doctor or pharmacist before taking this medicine if you:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

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

In some cases, your doctor may investigate the type of bacteria that is causing your infection.

Depending on the results, you may be given a different strength of Co-amoxiclav or a different medicine.

Conditions you need to look out for

Co-amoxiclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Co-amoxiclav, to reduce the risk of any problems. See 'Conditions you need to look out for' in **Section 4**.

Blood and urine tests

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Co-amoxiclav. This is because Co-amoxiclav can affect the results of these types of tests.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If you are taking allopurinol (used for gout) with Co-amoxiclav, it may be more likely that you'll have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-amoxiclav.

If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav then extra blood tests may be needed.

Co-amoxiclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Pregnancy and breast-feeding

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Co-amoxiclav can have side effects and the symptoms may make you unfit to drive.

Don't drive or operate machinery unless you are feeling well.

3 How to take Co-Amoxiclav

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

Adults and children weighing 40 kg and over

- The usual dose is:
- 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Co-amoxiclav oral suspension.

Ask your doctor or pharmacist for advice when giving Co-amoxiclav tablets to children weighing less than 40 kg.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Co-amoxiclav

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Co-amoxiclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

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draft: 44045261
laetus code: 4601
mat.no.: 46090651

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Proof no. 004.2	Date prepared: 30/05/2012	Prepared by: DW	
RA Approved? Yes	Date approved: 30/05/2012	Approved by: VM	
Colours: ■ Black <input type="checkbox"/>	<input type="checkbox"/>	Fonts: Helvetica	
Dimensions: 165 x 310 mm		Font size: 7pt	
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If you take more Co-amoxiclav than you should

If you take too much Co-amoxiclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

If you forget to take Co-amoxiclav

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose.

If you stop taking Co-amoxiclav

Keep taking Co-amoxiclav until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Co-amoxiclav can cause side effects, although not everybody gets them.

Conditions you need to look out for

Allergic reactions:

- skin rash
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse.

Contact a doctor immediately if you get any of these symptoms. **Stop taking Co-amoxiclav.**

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Contact your doctor as soon as possible for advice if you get these symptoms.

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
 - if affected take Co-amoxiclav before food
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests: Increase in some substances (enzymes) produced by liver.

Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - *erythema multiforme*)

If you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Steven-Johnson syndrome), and more severe form, causing extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)

- a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*)

Contact a doctor immediately if you get any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Co-Amoxiclav or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing.

Side effects that may show up in your blood or urine tests

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

If you get side effects

Tell your doctor or pharmacist if any of the side effects becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5 How to store Co-Amoxiclav

Do not store above 25°C.
Store in the original package.
Keep out of reach and sight of children.

Do not use Co-amoxiclav after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

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-amoxiclav contains:

The active ingredients of Co-amoxiclav Tablets are amoxicillin 500 mg as amoxicillin trihydrate and clavulanic acid 125 mg. This combination of antibiotics is also known as Co-amoxiclav.

Co-amoxiclav Tablets also contain: magnesium stearate (E572), talc, povidone, microcrystalline cellulose, croscarmellose sodium, triethyl citrate, ethyl cellulose, sodium lauryl sulphate, cetyl alcohol, hypromellose, and titanium dioxide (E171).

What Co-amoxiclav looks like and contents of the pack:

Co-amoxiclav Tablets are oval, convex, film-coated and off-white in colour. The tablets are scored on both sides. Co-amoxiclav Tablets come in packs of 21.

Marketing Authorisation Holder and Manufacturer


Marketing Authorisation Holder:
Sandoz Ltd,
Frimley Business Park, Frimley,
Camberley, Surrey, GU16 7SR, UK.

Manufacturer:
Sandoz GmbH,
A-6250 Kundl, Tyrol,
Austria.

This leaflet was last approved in 06/2010.

SZ88006LT01B
46090651

draft: 44045261
laetus code: 4601
mat.no.: 46090651

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Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom.			Ref: N015 - Address change, new printer		
T: 01276 698020 F: 01276 698324 W: www.uk.sandoz.com E: sandoz.artwork@me.com	Proof no. 004.2	Date prepared: 30/05/2012	Prepared by: DW		
	RA Approved? Yes	Date approved: 30/05/2012	Approved by: VM		
	Colours: ■ Black <input type="checkbox"/> <input type="checkbox"/>		Fonts: Helvetica		
	Dimensions: 165 x 310 mm		Font size: 7pt		
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