

PHARMACODE READING
DIRECTION

135 mm

135 mm

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-Amoxiclav

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

Dry powder

Store in the original package in order to protect from moisture.
Do not store above 25°C.

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

Liquid suspension

Store in a refrigerator (2°C - 8°C).
Do not freeze.

Once made up, the suspension should be used within 7 days.

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

6. Contents of the pack and other information

What Co-Amoxiclav contains

- The active substances are amoxicillin and clavulanic acid. Each 5 ml of suspension contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg of clavulanic acid.
- The other ingredients are Silica, Colloidal Hydrated, Aspartame (E951), Succinic acid, Xanthan gum, Hypromellose, Colloidal anhydrous silica, Strawberry guarana flavour (including maltodextrin).
- See "Co-Amoxiclav contains aspartame" in section 2.

What Co-Amoxiclav looks like and contents of the pack

Co-Amoxiclav 250/62.5 mg/5 ml Oral Suspension is a White to off-white granular powder supplied in a translucent HDPE bottle with polypropylene cap. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close,
Hounslow West
Middlesex, TW4 5DQ
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Co-Amoxiclav 250-62.5mg/5ml Powder for Oral Suspension

DE: Amoxicillin/Clavulansäure Micro Labs 250 mg /5 ml + 62,5 mg /5 ml Pulver zur Herstellung einer Suspension zum Einnehmen

This leaflet was last approved on 04/2017

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.



Pharma Code



BROWN & BURK

Package leaflet: Information for the user

Co-Amoxiclav 250mg / 62.5mg / 5 ml powder for oral suspension (Amoxicillin / clavulanic acid)

Read all of this leaflet carefully before you start using this medicine because it contains important information for them.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine is usually prescribed for a baby or child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If you notice any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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 babies 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. What you need to know before you use Co-Amoxiclav

Do not use Co-Amoxiclav to your child:

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

Do not use Co-Amoxiclav to your child if any of the above apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Co-Amoxiclav.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Co-Amoxiclav if your child:

- has glandular fever
- is being treated for liver or kidney problems
- is not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Co-Amoxiclav.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child 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 your child is taking Co-Amoxiclav, to reduce the risk of any problems. See 'Conditions you need to look out for' in section 4.

Blood or urine tests

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

Other medicines and Co-Amoxiclav

Tell your doctor or pharmacist if your child is using, has recently used or might use any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If your child is taking allopurinol (used for gout) with Co-Amoxiclav, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the 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.



Pharma Code

BBUK Code Artwork Code

Front Side

Size: 270 x 250 mm

PHARMACODE READING
DIRECTION

270 mm

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

Co-Amoxiclav may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Co-Amoxiclav can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Co-Amoxiclav contains aspartame (E951) and maltodextrin:

- Co-Amoxiclav contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.
- Maltodextrin is absorbed as glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Co-Amoxiclav

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg or over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you how much Co-Amoxiclav you should give to your baby or child.
- You may be provided with or without a measuring syringe. You should use this to give the correct dose to your baby or child.
- Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Co-Amoxiclav

- Always shake the bottle well before each dose
- Give 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 give your child Co-Amoxiclav for more than 2 weeks. If your child still feels unwell they should

go back to see the doctor.

If you use more Co-Amoxiclav than you should

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

If you forget to use Co-Amoxiclav

Do not give a double dose to make up for a forgotten dose.

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

If your child stops taking Co-Amoxiclav

Keep giving your child Co-Amoxiclav until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

Instructions for reconstitution

Check cap seal is intact before using. Shake the bottle to loosen powder then fill the bottle with water to just below the line on the bottle. Invert and shake well, then top up with water exactly to the line. Invert and again shake well.

Shake the bottle well before each dose.

The tables below contains dosing information in mL suspension dependent on the weight of the child (5 ml = 250 mg Amoxicillin + clavulanic acid 62.5 mg):

| Approximate age | Body weight (Kg) | Dosage based 20 mg / 5 mg / kg / day to 40 mg / 10 mg / kg / day | Dosage based 60 mg / 15 mg / kg / day |
|-----------------|------------------|--|---------------------------------------|
| 1-1.5 years | 10-11 | 1.25 ml 3 times a day to 2.5 ml 3 times a day. | * |
| 2-3 years | 12-13 | 1.5 ml 3 times a day to 3 ml 3 times a day. | * |
| | 14-15 | 1.5 ml 3 times a day to 4 ml 3 times a day. | 5-6 ml 3 times a day |
| 3-5 years | 16-17 | 2 ml 3 times a day to 4.5 ml 3 times a day. | 6-6.5 ml 3 times a day |
| | 18-19 | 2 ml 3 times a day to 5 ml 3 times a day. | 7-7.5 ml 3 times a day |
| 5-7 years | 20-21 | 2.5 ml 3 times a day to 5 ml 3 times a day. | 8 ml 3 times a day |
| | 22-23 | 2.5 ml 3 times a day to 6 ml 3 times a day. | 8.5-9 ml 3 times a day |
| | 24-25 | 3 ml 3 times a day to 6.5 ml 3 times a day. | 9-10 ml 3 times a day |
| 7-9 years | 26-27 | 3 ml 3 times a day to 7 ml 3 times a day. | 10 ml 3 times a day |
| | 28-29 | 3.5 ml 3 times a day to 7.5 ml 3 times a day. | 11 ml 3 times a day |

| | | | |
|-------------|-------|---|------------------------|
| 10-11 years | 30-31 | 4 ml 3 times a day to 8 ml 3 times a day. | 12 ml 3 times a day |
| | 32-33 | 4 ml 3 times a day to 8.5 ml 3 times a day. | 12-13 ml 3 times a day |
| | 34-35 | 4.5 ml 3 times a day to 9 ml 3 times a day. | 13-14 ml 3 times a day |
| 11-12 years | 36-37 | 4.5 ml 3 times a day to 9.5 ml 3 times a day. | 14 ml 3 times a day |
| | 38-39 | 5 ml 3 times a day to 10 ml 3 times a day. | 15 ml 3 times a day |

* No clinical data is available for this dosage for children less than 2 years.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

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 your child gets 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 your child gets these symptoms.

Very common:

- May affect more than 1 in 10 people
- diarrhoea (in adults).

Common:

- 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:

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 blood tests:

- increase in some substances (enzymes) produced by the liver.

Rare:

May affect up to 1 in 1,000 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 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)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a 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 your child gets 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 child's 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 blood or urine tests:

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

Reporting of side effects

If your child gets any side effects talk to your doctor,

250 mm