

**Co-amoxiclav 400/57 mg/5 ml Powder for Oral Suspension**

Amoxicillin/clavulanic acid

**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 side effects, talk to your doctor or pharmacist. 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 take Co-amoxiclav
3. How to take 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 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. What you need to know before you give Co-amoxiclav****Do not give your child Co-amoxiclav:**

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

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

**Warnings and precautions:**

Talk to your doctor or pharmacist before giving your child this medicine if they:

- 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 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 and urine tests**

If your child is 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 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 taking, has recently taken or might take any other 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), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

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

Methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

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

**Pregnancy, breast-feeding and fertility:**

If your child who is about to take this medicine is pregnant or breast-feeding, thinks it may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Co-amoxiclav 400/57 mg/5 ml Powder for Oral Suspension contains aspartame, sorbitol, glucose, benzyl alcohol and sodium

This medicine contains 1.7 mg aspartame in 1 ml of reconstituted suspension. Aspartame is a source of phenylalanine. This may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 0.03 mg sorbitol and 0.21 mg glucose in 1 ml of reconstituted suspension. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine.

This medicine contains 0.11 mg benzyl alcohol in 1 ml reconstituted suspension.

Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

This medicine contains less than 1 mmol (23 mg) sodium in 1 ml reconstituted solution, that is to say essentially sodium-free.

**3. How to give Co-amoxiclav**

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

**Adults and children weighing 40 kg and 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 a plastic measuring spoon or syringe doser. You should use this to give the correct dose to your baby or child.
- Usual dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

**Patients with kidney and liver problems**

- If your child has kidney problems the dose might be changed. 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 check how their liver is working.

**How to give Co-amoxiclav**

- Always shake the bottle well before each dose
- Give with a meal
- 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.

*Continued on the next page >>*

**Instructions for reconstitution**

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At time of dispensing, the dry powder should be reconstituted to form an oral suspension, as detailed below:

After opening of the screw cap, ensure that the bottle cap seal is intact and tightly attached to the bottle rim. Do not use if not intact.

Remove the membrane carefully and completely and discard before reconstituting the product. Fill the bottle with water to just below the mark on the label and shake well at once. Then add water exactly to the mark and shake vigorously again. Shake the bottle well before every withdrawal.

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#### **If you give 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 give Co-amoxiclav**

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. Do not take a double dose to make up for a forgotten 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. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine 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 throat (angioedema), causing difficulty in breathing
- collapse
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

**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.

##### **Acute inflammation of the pancreas (acute pancreatitis)**

If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

##### **Drug-induced enterocolitis syndrome (DIES):**

DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

##### **Very common side effects** (may affect more than 1 in 10 people)

- diarrhoea (in adults).

##### **Common side effects** (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 give Co-amoxiclav with a meal.
- vomiting
- diarrhoea (in children).

##### **Uncommon side effects** (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 the liver

##### **Rare side effects** (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 your blood tests:**

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

##### **Frequency not known** (frequency cannot be estimated from the available data)

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)
- Crystals in urine leading to acute kidney injury
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the membranes that surround the brain and

spinal cord (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 (exanthematous pustulosis)
  - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

#### **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)

##### **Reporting of side effects**

If your child gets 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 ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)) or search for MHRA Yellow Card in Google play or Apple App store. 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.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. Store in the original container. Keep the container tightly closed.

The reconstituted suspension should be stored in a refrigerator (2°-8° C) and used within 7 days.

Do not use this medicine if lumps of powder are visible in the bottle before reconstitution.

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 ml reconstituted suspension contains 80 mg amoxicillin (as trihydrate) and 11.4 mg clavulanic acid (as potassium clavulanate)

The other ingredients are: anhydrous citric acid, anhydrous trisodium citrate, aspartame (E 951), talc, guar, silicon dioxide, lemon flavouring (natural flavouring materials, nature-identical flavouring materials, dextrose, maltodextrin, butylated hydroxyanisole (E 320), sorbitol syrup (E 420), acacia gum (E 414), peach-apricot flavouring (natural flavouring materials, nature-identical flavouring materials, maltodextrin, butylated hydroxyanisole (E 320), sorbitol syrup (E 420), acacia gum (E 414), orange flavouring (nature-identical flavouring materials, artificial flavouring substances, maltodextrin, alpha-tocopherol (E 307), benzyl alcohol).

##### **What Co-amoxiclav looks like and contents of the pack**

Co-amoxiclav powder for oral suspension is an off-white powder.

The powder for oral solution is packed in an amber glass bottle (type III), 60 ml, 120 ml and 150 ml, with mouth design for screw closure. Screw closure, child-resistant, with sealing liner, embossed. Graduated syringe (5 ml) for 60 ml bottles (for pack sizes of 35 ml, 50 ml, 60 ml suspension)

Measuring spoon (5 ml) for 120 ml bottles (for pack sizes of 70 ml, 75 ml, 100 ml suspension) and 150 ml bottles (for a pack size of 140 ml suspension)

Original packs for preparing of 35, 50, 60, 70, 75, 100 and 140 ml suspension.

Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorization Holder:** Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL United Kingdom

**Manufacturer:** Sandoz GmbH, Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria

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31.9 ml of water is added in order to get 35 ml prepared oral suspension.  
45.5 ml of water is added in order to get 50 ml prepared oral suspension.  
54.6 ml of water is added in order to get 60 ml prepared oral suspension.  
63.7 ml of water is added in order to get 70 ml prepared oral suspension.  
68.3 ml of water is added in order to get 75 ml prepared oral suspension.  
89.3 ml of water is added in order to get 100 ml prepared oral suspension.

125.0 ml of water is added in order to get 140 ml prepared oral suspension.

Do not use the reconstituted suspension if the colour is not off-white.

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