

PACKAGE LEAFLET

Package leaflet: Information for the user

Co-amoxiclav Sugar Free 200mg/28.5mg/5ml Powder for Oral Suspension
Co-amoxiclav Sugar Free 400mg/57mg/5ml Powder for Oral Suspension

Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start giving your child 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's.
- If your child gets any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
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What is in this leaflet:

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

1. What Co-amoxiclav sugar free suspension is and what it is used for

Co-amoxiclav Sugar Free Suspension 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 Sugar Free Suspension 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.

You must talk to a doctor if your child does not feel better or if your child feels worse.

2. What you need to know before you give Co-amoxiclav sugar free suspension

Do not give your child Co-amoxiclav Sugar Free Suspension:

- if they are allergic (hypersensitive) 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 (hypersensitive) 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 Sugar Free Suspension to your child if any of the above apply to your child.

If you are not sure, talk to their doctor, pharmacist or nurse before giving Co-amoxiclav Sugar Free Suspension.

Take special care with Co-amoxiclav Sugar Free Suspension

Check with their 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 Sugar Free Suspension.

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 Sugar Free Suspension or a different medicine.

Conditions you need to look out for

Co-amoxiclav Sugar Free Suspension 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 Sugar Free Suspension, 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 (for glucose), let the doctor or nurse know that they are taking Co-amoxiclav Sugar Free Suspension. This is because Co-amoxiclav Sugar Free Suspension can affect the results of these types of tests.

Other medicines and Co-Amoxiclav Sugar Free Suspension

Tell your doctor or pharmacist if your child is taking, has recently taken or might take 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 Sugar Free Suspension, 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 Sugar Free Suspension.
- If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav Sugar Free Suspension then extra blood tests may be needed.
- Co-amoxiclav Sugar Free Suspension can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Co-amoxiclav Sugar Free Suspension can 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 they 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 Sugar Free Suspension can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

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

Co-amoxiclav Sugar Free Suspension contains aspartame and maltodextrin:

- Co-amoxiclav Sugar Free Suspension contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly
- Co-amoxiclav contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to give Co-amoxiclav sugar free suspension

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

The recommended dose is:

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 body weight in kilograms.

- Your doctor will advise you how much Co-amoxiclav Sugar Free Suspension you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.
- Recommended 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 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 Sugar Free Suspension

- 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 Sugar Free Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Co-amoxiclav Sugar Free Suspension than you should

If you give your child too much Co-amoxiclav Sugar Free Suspension, 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 Sugar Free Suspension

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 Sugar Free Suspension

Keep giving your child Co-amoxiclav Sugar Free Suspension 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, 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 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 Sugar Free Suspension.

Inflammation of large intestine

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

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/clavulanic acid. 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.

Contact your doctor as soon as possible for advice if your child gets 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 Sugar Free Suspension 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 blood tests:

- increase in some substances (*enzymes*) produced by the 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 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 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 (*exanthemous 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)).
 - Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
 - A red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).

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 Sugar Free Suspension 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 leading to acute kidney injury.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Co-amoxiclav sugar free suspension

Dry powder: This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not use if the powder is discoloured.

After reconstitution: Store in a refrigerator between 2°C to 8°C in the container supplied and use within 7 days.

Shake well before use.

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.

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 to protect the environment.

6. Contents of the pack and other information

What Co-amoxiclav Sugar Free Suspension contains

- Co-amoxiclav Sugar Free *200mg/28.5mg/5ml* Powder for Oral Suspension contains 200mg of amoxicillin (as amoxicillin trihydrate) and 28.5mg of Clavulanic acid (as potassium clavulanate) in every 5 ml of reconstituted product.
- Co-amoxiclav Sugar Free *400mg/57mg/5ml* Powder for Oral Suspension contains 400mg of amoxicillin (as amoxicillin trihydrate) and 57mg of Clavulanic acid (as potassium clavulanate) in every 5 ml of reconstituted product.

The active substances are amoxicillin trihydrate and potassium clavulanate

The other ingredients are:

- Silicon dioxide (E551)
- Aspartame (E951)
- Succinic acid (E363)
- Xanthan gum (E415)
- Hypromellose (E464)

- Colloidal anhydrous silica (E551)
- Raspberry Flavour [Acacia gum (E414), Nature identical flavouring substance, Propylene glycol (E1520), Artificial flavouring substance and Flavouring preparation]
- Orange Flavour [Acacia gum (E414), Flavouring preparation and Butylated hydroxyanisole (E320)]
- Golden Caramel [Maltodextrin, Triethyl Citrate (E1505), Artificial Flavours and Acetic acid (E260)]

What Co-amoxiclav Sugar Free Suspension looks like and contents of the pack

Co-amoxiclav Sugar Free powder for Oral Suspension is a white to off-white dry powder, which when reconstituted as directed, yields a white to off-white suspension with a mixed fruit flavour.

This product is available in plastic bottles with a CRC cap as follows:

- 60ml bottle containing 30ml of reconstituted suspension.
- 115ml bottle containing 60ml of reconstituted suspension.
- 115ml bottle containing 70ml of reconstituted suspension.
- 150ml bottle containing 100ml of reconstituted suspension.

Each pack may be supplied with a 5 ml oral syringe made from polystyrene.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Brown & Burk IR Limited
22 Northumberland Road,
Ballsbridge, Dublin 4, Ireland

Manufacturer

Misom Labs Ltd
Malta Life Sciences Park,
LS2.01.06, Industrial Estate, San Gwann, SGN 3000, Malta

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

UK : Co-amoxiclav Sugar Free 200 mg/28.5 mg/5 ml Powder for oral suspension
Co-amoxiclav Sugar Free 400 mg/57 mg /5 ml Powder for oral suspension

IE : Co-amoxiclav Sugar Free 200 mg/28.5 mg/5 ml Powder for oral suspension
Co-amoxiclav Sugar Free 400 mg/57 mg /5 ml Powder for oral suspension

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