Package leaflet: Information for the patient

Trade name of the medicinal product:
Amoksiklav® 156.25 mg/5 ml Powder for oral suspension
Amoksiklav® 312.5 mg/5 ml Powder for oral suspension

International nonproprietary name: 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, nurse 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 Amoksiklav is and what it is used for

Amoksiklav 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.

Amoksiklav 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 take Amoksiklav

Do not take Amoksiklav:
- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6),
- if you have ever had a severe allergic (hypersensitivity) reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat,
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take Amoksiklav if any of the above apply to you (or your child).
If you are not sure, talk to your doctor or pharmacist before taking Amoksiklav.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you (or your child):
- 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 (or your child), talk to your doctor or pharmacist before taking Amoksiklav.

In some cases, your doctor may investigate the type of bacteria that is causing the infection. Depending on the results, you may be given a different strength of Amoksiklav or a different medicine.

Conditions you need to look out for
Amoksiklav 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 Amoksiklav, 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 Amoksiklav. This is because Amoksiklav can affect the results of these types of tests.

Other medicines and Amoksiklav
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or are going to take/use any other medicines.

If you are taking **allopurinol** (used for gout) with Amoksiklav, 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 Amoksiklav.

If medicines to help stop blood clots (such as **warfarin or acenocoumarol**) are taken with Amoksiklav then extra blood tests may be needed.

Amoksiklav can affect how **methotrexate** (a medicine to treat cancer or rheumatic diseases) works.

Amoksiklav may affect how **mycophenolate mofetil** (a medicine 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
Amoksiklav can have side effects and the symptoms that may make you unfit to drive.
Don't drive or operate machinery unless you are feeling well.

Amoksiklav contains aspartame, potassium, sodium.
156.25 mg/5 ml: Each ml of the reconstituted suspension contains 1.7 mg of aspartame (E951) and 1.35 mg of potassium.
321.5 mg/5 ml: Each ml of the reconstituted suspension contains 3.3 mg of aspartame (E951) and 2.7 mg of potassium.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.
Potassium content is be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
This medicines contain less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.
These medicines contain maltodextrin (glucose) in the strawberry flavouring. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these medicinal products.

3. How to take Amoksiklav

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

Adults and children with bodyweight of 40 kg and above
• Other, higher-dose dosage forms are recommended. Ask your doctor or pharmacist for advice.
• One 500 mg/125 mg dose three times a day.

Children with bodyweight under 40 kg
All doses are calculated based on the child's body weight in kilograms.
- Your doctor will advise you on how much Amoksiklav to give to your child.
- Use the enclosed measuring syringe to give the correct dose to your child.
- The recommended dose is 20 mg/5 mg to 60 mg/15 mg per kilogram of bodyweight per day and is to be taken in three divided doses.

Patients with kidney or liver problems
- If you have kidney problems the dose might be reduced. 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.

Method of administration
- For oral use after the reconstitution of suspension.
- Always shake the bottle well before each use.
- Take at the start of a meal.
- Take the doses evenly throughout the day, at least 4 hours apart. Do not take 2 doses in an hour.
- Do not take Amoksiklav for more than 2 weeks. See your doctor again if you don't feel better.

For reconstitution of the suspension, please see the end of the package leaflet.

<u>Withdrawal of the ready-to-use suspension using a dosing syringe</u>
- Shake the bottle before each withdrawal.

- Press the enclosed adapter (plug with an opening) into the neck of the bottle. The adapter connects the dosing syringe with the bottle and remains in the bottle neck.
- Insert the dosing syringe firmly into the adapter. The plunger should be inserted into the syringe as far as it will go.
- Carefully turn the bottle with the attached dosing syringe upside down. Slowly pull the plunger down to get the prescribed volume in milliliters (ml). If there are air bubbles in the drawn up suspension, push the plunger back into the syringe and refill slowly.
- Place the bottle with the attached dosing syringe upright again and pull the syringe out of the adapter.

Intake of the ready-to-use suspension with a dosing syringe

- The suspension can be emptied directly from the dosing syringe into the mouth or given on a spoon to take.
- The patient should sit upright when the medicine is administered directly from the dosing syringe into the mouth.
- Close the bottle tightly after each use. After use, wash the dosing syringe by filling it with clean water several times.

Keep the ready-to-use suspension in the refrigerator (2° C – 8°C).

If you take more Amoksiklav than you should
If you take too much Amoksiklav, 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 Amoksiklav
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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amoksiklav
Keep taking Amoksiklav 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 medicine, ask your doctor or pharmacist.

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 lymph glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse.

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

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.

Common side effects (may affect up to 1 in 10 patients)

- Fungal infection (Candida - yeast infection of the vagina, mouth or skin folds)
- Nausea, especially with high doses
- → To reduce gastrointestinal reactions, take the medicine at the start of a meal.
- vomiting
- diarrhea.

Uncommon side effects (may affect up to 1 in 100 patients)

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

Uncommon side effects that may show up in blood tests:

- An increase in some substances (enzymes) produced by the liver, indicating liver damage

Rare side effects (may affect up to 1 in 1,000 patients)

- 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)

- overgrowth of non-susceptible organisms
- 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 (*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 you get any of these symptoms.**

- inflammation of the liver (*hepatitis)*
- jaundice, caused by increases of bilirubin (a substance produced in the liver) in the blood, 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 Amoksiklav or who have kidney problems)
- black tongue which looks hairy
- staining of teeth, which is 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.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the national reporting system on adverse drug reactions and drug inefficacy identified on the territory of the Member State of the Eurasian Economic Union.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amoksiklav

Keep out of reach and sight of children.

Shelf life: 3 years.

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

Powder for oral suspension should be stored below 30 °C.
Do not use this medicine if lumps of powder are visible in the bottle before reconstitution.

Reconstituted suspension should be stored tightly closed at a temperature 2–8 °C and 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 Amoksiklav contains
The active substances are amoxicillin and clavulanic acid.

Each 5 ml of Amoksiklav 156.25 mg/5 ml oral suspension contains 125 mg of amoxicillin in the form of amoxicillin trihydrate and 31.25 mg of clavulanic acid in the form of potassium clavulanate.

Each 5 ml of Amoksiklav 312.5 mg/5 ml oral suspension contains 250 mg of amoxicillin in the form of amoxicillin trihydrate and 62.5 mg of clavulanic acid in the form of potassium clavulanate.

The other ingredients are:
silica, colloidal anhydrous, xanthan gum, crospovidone, aspartame (E951), carmellose sodium, silicon dioxide, strawberry flavouring.

What Amoksiklav looks like and contents of the pack
Amoksiklav powder for oral suspension is white to cream coloured powder.
After reconstitution the suspension is homogeneous, white to cream coloured.

A carton pack contains:
- an amber glass bottle closed with a screw closure with a sealing liner;
  A bottle contains:
  - 7.88 g of powder for reconstitution of 100 ml of Amoksiklav® 156.25 mg/5 ml suspension
  - 15.8 g of powder for reconstitution of 100 ml of Amoksiklav® 312.5 mg/5 ml suspension
- a dosing syringe (with markings from 0.5 ml to 5 ml) made of polyethylene/ polypropylene with an adapter made of polyethylene.
- a Package Leaflet.

Prescription Status
Available on prescription.

Marketing Authorisation Holder
Lek d.d., Verovškova Str. 57, 1526 Ljubljana, Slovenia.

Manufacturer
Sandoz GmbH, Biochemiestraße 10, A-6250, Kundl, Austria.

This leaflet was last revised in April 2023.

Consumers' claims could be addressed to e-mail: drugsafety.cis@novartis.com

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Advice/medical information
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.

Reconstitution

Generally, suspension is prepared by a pharmacist in the pharmacy. After reconstitution the ready-for-use suspension is white to cream coloured.

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

After opening the screw cap, make sure that the seal on the cap is intact and that it is on the bottle neck. Shake the bottle to loosen the powder. Add the volume of water (as indicated below) in two portions (first to 2/3 and then to the mark) and shake well each time. Shake the contents of the bottle well before each use.

	Volume of water to be added into a 100 ml vial presentation for reconstitution of suspension
Amoksiklav powder for oral suspension 156.25 mg/5 ml	98 ml
Amoksiklav powder for oral suspension 312.5 mg/5 ml	94 ml

Do not use the reconstituted suspension if the colour is not white to cream coloured.

Shake the contents of the bottle well before each use.