Package leaflet: Information for the patient

Trade name of the medicinal product:
Amoksiklav® 625 mg Film-coated tablets
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. 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:

- 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 Amoksiklav.

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 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, have recently taken or might take 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 Amoksiklav, it may be more likely that you will 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.
Do not drive or operate machinery unless you are feeling well.

The medicine contains sodium.
This medicine contains less than 1 mmol (23 mg) sodium per a film-coated tablet, that is to say essentially 'sodium-free'.

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
The recommended dose is:
- 1 tablet three times a day.

Children with bodyweight under 40 kg
Children aged 6 years or less should preferably be treated with Amoksiklav oral suspension.

Ask your doctor or pharmacist for advice when giving Amoksiklav tablets to children with bodyweight under 40 kg.

Patients with kidney or 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.

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

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 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.

Very common side effects (may affect more than 1 in 10 people)
- diarrhoea.

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.
  →To reduce gastrointestinal reactions, take the medicine at the start of a meal.
- vomiting.

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.

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

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 this medicine out of the sight and reach of children.

Shelf life: 2 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.

Do not store above 30 °C.
Store in the original package in order to protect from moisture.
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 tablet contains 500 mg of amoxicillin in the form of amoxicillin trihydrate and 125 mg of clavulanic acid in the form of potassium clavulanate.
The other ingredients are:
Core
Colloidal anhydrous silica, Magnesium Stearate, Sodium Starch Glycolate (Type A), Microcrystalline Cellulose.
Coating
Triethyl Citrate, Hypromellose, Talc, Ethylcellulose, aqueous dispersion, Titanium Dioxide (E171).

What Amoksiklav looks like and contents of the pack
White to slightly yellowish, oblong, biconvex film-coated tablets with the embossment GG N6 on one side.
There are 10 (2x5) or 15 (3x5) tablets (in Al/Al blisters) packed in a carton together with 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 June 2021.

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

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.