

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with
a doctor's prescription only

Amoxiclav Teva®

875 mg

Film-coated tablets

Each Film-coated tablet contains:

Amoxicillin (as trihydrate) 875 mg
Clavulanic acid (as potassium salt) 125 mg

For information on the inactive ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Amoxiclav Teva 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.

Amoxiclav Teva is an antibiotic that 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" whose activity can sometimes stop (made inactive). The other active component (clavulanic acid) prevents this from happening.

Therapeutic group

Amoxicillin: Antibiotic from the penicillin group.

Clavulanic acid: Beta-lactamase enzyme inhibitors.

2. BEFORE USING THE MEDICINE

❑ Do not use the medicine if:

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

Do not take Amoxiclav Teva if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Amoxiclav Teva.

Special warnings regarding the use of the medicine

Talk to your doctor or pharmacist before taking Amoxiclav Teva if:

- you have glandular fever
- you are being treated for liver or kidney problems
- you are not passing water **properly**.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Amoxiclav Teva.

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

⚠ Conditions you need to look out for

Amoxiclav Teva 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 Amoxiclav Teva, 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 undergoing blood tests (such as red blood cell status tests or liver function tests) or urine tests (for checking glucose levels), let the doctor know that you are taking Amoxiclav Teva. This is because Amoxiclav Teva can affect the results of these types of tests.

⚠ Other medicines and Amoxiclav Teva
If you are taking, have recently taken or might take other medicines including non-prescription medicines, herbal medicines and nutritional supplements, tell the doctor or the pharmacist. Especially:

- If you are taking allopurinol (used for gout) with Amoxiclav Teva, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), the doctor may change the dosage of the Amoxiclav Teva.
- If medicines that help prevent blood clotting (such as warfarin or acenocoumarol) are taken with Amoxiclav Teva then extra blood tests may be needed.
- Amoxiclav Teva can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Amoxiclav Teva 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 become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

⚠ Driving and using machines

Amoxiclav Teva can have side effects and the symptoms may cause you to be unfit to drive. Do not drive or operate machinery unless you are feeling well.

⚠ Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation as per the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined only by the doctor.

Adults and children weighing 40 kg and over

- The usual dosage is generally: 1 tablet, twice a day
- A higher dosage: 1 tablet, three times a day

Children weighing less than 40 kg

It is advisable to treat children aged six and under with the oral suspension. Consult with the doctor when giving tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

There are no clinical data for patients under the age of 2 months.

Patients with kidney and 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 need to perform more frequent blood tests to check your liver function.

Do not exceed the recommended dose.

How to take Amoxiclav Teva

- Swallow the tablets whole, with a glass of water, with a meal.
- Tablets can be halved along the score line to ease swallowing. Take both pieces of the tablet at the same time. There is no information regarding crushing, chewing or pulverizing the tablet.
- Space the doses evenly throughout the day, at least 4 hours apart. Do not take 2 doses in one hour.
- Do not take Amoxiclav Teva for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you accidentally have taken a higher dosage

If you accidentally have taken too much Amoxiclav Teva, the signs might include stomach discomfort (nausea, vomiting or diarrhea) or convulsions (fits). Refer to your doctor as soon as possible. Take the medicine package to show the doctor.

If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Amoxiclav Teva

- If you forgot 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.

Persist with the treatment as recommended by the doctor.

If you stop taking Amoxiclav Teva

Keep taking Amoxiclav Teva until the treatment is finished, even if you feel better. Each dose is important for you in order to fight the infection successfully. If some bacteria survive they may cause the infection to come back.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Amoxiclav Teva may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them. The side effects below may occur with this medicine.

Conditions you need to look out for:

Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may appear 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 breathing difficulties
- collapse.

Refer to a doctor immediately if you experience any of these symptoms. **Stop taking Amoxiclav Teva.**

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea usually accompanied by blood and mucus, stomach pain and/or fever.

Refer to your doctor as soon as possible for advice if you experience these symptoms.

Additional side effects

Very common side effects

These may occur in more than 1 in 10 people

- diarrhea (in adults).

Common side effects

These may occur in up to 1 in 10 people

- thrush (*candida* - a fungal infection of the vagina, mouth or skin folds)
- nausea, especially when taking a high dosage. If nausea occurs, take Amoxiclav Teva with a meal
- vomiting
- diarrhea (in children).

Uncommon side effects

These may occur in 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 liver enzymes.

Rare side effects

These may occur in up to 1 in 1,000 people

- skin rash, which may include blisters (looks like central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*).

If you notice any of these symptoms, refer to 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.

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- 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 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 an increase in the amount of white blood cells [eosinophilia] and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms [*DRESS*]).

Refer to a doctor immediately if you experience any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by an increase of bilirubin in the blood (a substance produced in the liver) which may cause yellowing of your skin and whites of the eyes
- inflammation of tubes in the kidney
- longer blood clotting time
- hyperactivity
- convulsions/fits (in people taking high doses of Amoxiclav Teva or who have kidney problems)
- black tongue which looks hairy.

Side effects that may show up in your blood or urine tests:

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

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- Do not use if the tablets are cracked or damaged.
- Do not discard medicines into the wastewater or household waste. Consult the pharmacist on how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

- What Amoxiclav Teva contains:
In addition to the active ingredients the medicine also contains:
Tablet core –
Microcrystalline cellulose, sodium starch glycolate, colloidal silica anhydrous, magnesium stearate.
Film-coat –
Hypromellose 5 cp (E464), titanium dioxide (E171), macrogol PEG-400, hypromellose 15 cp (E464).
Each Amoxiclav Teva tablet contains 0.6 mg sodium.
- What the medicine looks like and the content of the package:
White-colored, capsule-shaped, film-coated tablets, debossed with "A" on one side and with a score line in between '6' and '5' on the other side.
The marketed package contains 14 tablets.
- Name of License Holder and its Address:
Abic Marketing Ltd., P.O.B. 8077, Netanya.
- Name of Manufacturer and its Address:
Aurobindo Pharma Limited, India.
Survey 314, R.R. district, Hyderabad Telangana state, 500 090, India.
- This leaflet was checked and approved by the Ministry of Health in July 2015 and was updated in July 2018 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 146.13.33189

teva

AMOX CTAB PL SH 260818