

Patient Information Leaflet
Ipiclav-625
Amoxicillin & Potassium Clavulanate Tablets BP
Co-Amoxiclav BP

The information in this leaflet applies only to Ipiclav-625 Tablets. Please read this entire leaflet carefully before you start taking this medicine. It contains important information about the treatment. Keep this leaflet with you as you may need to read it again. If you have any further questions or are not sure about anything, ask your doctor, health care provider or pharmacist.

REMEMBER: This medicine has been prescribed for you. Do not pass this medicine to others. It may harm them, even if they have the same symptoms as you.

WHAT IS IN THIS LEAFLET

1. What Ipiclav-625 Tablets are and what they are used for

Ipiclav-625 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.

Ipiclav-625 is used in adults and children to treat the following infections:

- Middle ear and sinus infections
- Respiratory tract infections
- Urinary tract and kidney infections
- Skin and soft tissue infections including animal bites and dental infections
- Bone and joint infections.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Ipiclav-625

Do not take Ipiclav-625:

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

Do not take Ipiclav-625 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ipiclav-625 Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ipiclav-625 Tablets 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 these tablets.

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 Ipiclav tablets or a different medicine.

Conditions you need to look out for:

Ipiclav-625 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 Ipiclav-625, to reduce the risk of any problems.

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 Ipiclav-625. This is because Ipiclav-625 can affect the results of these types of tests.

Other medicines and Ipiclav-625 Tablets

Tell your doctor or pharmacist if you are using, have recently used or might use 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 Ipiclav-625, 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 Ipiclav-625.

If medicines to help stop blood clots (such as warfarin) are taken with Ipiclav-625 then extra blood tests may be needed.

Ipiclav-625 can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Ipiclav-625 can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organ) works.

It can also affect how oral contraceptives work.

This medicine contains potassium. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Pregnancy and breast-feeding

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.

You should only use Ipiclav-625 whilst pregnant if your doctor tells you to. This medicine may be harmful to the baby.

Amoxicillin and clavulanic acid can pass into breast milk. If you breast-feed while taking this medicine, your baby may be more likely to get diarrhoea or an infection. You should only use Ipiclav-625 whilst breastfeeding if your doctor tells you to.

Driving and using machines

Ipiclav-625 can have side effects, such as allergic reactions, dizziness or fits and the symptoms may make you unfit to drive.

Don't drive or operate machinery unless you are feeling well.

3. How to take Ipiclav-625

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

Adults and children weighing 40 kg and over

Usual dose - 1 tablet two times a day

For more severe infections and infections of the respiratory tract - 1 tablet three times a day

Children weighing less than 40 kg

Ask your doctor or pharmacist for advice when giving Ipiclav-625 tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Other forms of this medicine may be more suitable for children under 25 kg; ask your doctor or pharmacist.

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 have more frequent blood tests to check how your liver is working.

How to take Ipiclav-625 Tablets

- Take with a meal.
- Swallow the tablets whole with a glass of water.
- Do not take Ipiclav-625 for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Ipiclav-625 Tablets than you should

If you take too much Ipiclav-625 Tablets, 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 Ipiclav-625 Tablets

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

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hours before taking the next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Ipiclav-625 Tablets

Keep taking Ipiclav-625 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.

Serious side effects

Stop taking Ipiclav-625, contact a doctor immediately or go to your nearest hospital emergency department if you get any of the following:

Allergic reactions:

Uncommon (may affect up to 1 in 100 people)

- Skin rash

Rare (may affect up to 1 in 1000 people)

- Skin rash, which may, blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)

Not known (frequency cannot be estimated from available data)

- 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.
- a widespread red 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))

The following serious side effects have also been reported:

Very common (may affect up to more than 1 in 10 people)

- Diarrhoea, possibly with blood or mucus, stomach pain or fever

Rare (may affect up to 1 in 10,000 people)

- frequent infections causing fever, severe chills, sore throat or mouth ulcers (these may be signs of a low number of white blood cells).
- unexplained bruising or bleeding more easily or for longer than normal (these may be signs of a low number of cells involved in blood clotting).

Not known (frequency cannot be estimated from the available data)

- inflammation of the liver (hepatitis)
- Jaundice caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- convulsions (especially if you take high doses of Ipiclav-625 or if you have kidney problems).
- Sensitivity to light, stiff neck, body ache, sore throat, severe headache, flu like symptoms. These may indicate you have a type of meningitis that cannot be passed on to others caused by inflammation of the protective membrane surrounding the brain (aseptic meningitis).
- tiredness, headaches, shortness of breath when exercising, dizziness, pale or yellowing of the skin or eyes, these may be signs of a low number of red blood cells (hemolytic anemia).
- pain passing urine, lower back pain or fever. These may be signs of a serious kidney problem (interstitial nephritis)

Other side effects

Common (may affect up to 1 in 10 people)

- thrush (candida - a yeast infection of the vagina, mouth or skin folds).
- feeling sick (nausea), especially if you take high doses. If affected, take Ipiclav-625 with food.
- being sick (vomiting).

Uncommon (may affect up to 1 in 100 people)

- indigestion.
- dizziness.
- headache.
- increase in some substances (enzymes) produced by the liver

Not Known (frequency cannot be estimated from the available data)

- other infections that are difficult to treat (over-growth of non-susceptible organisms).
- hyperactivity.
- black tongue which looks hairy.
- crystals in urine (seen as cloudy urine or in a urine test)

5. How to store Ipiclav-625

Keep this medicine out of the sight and reach of children.

Store below 30°C in a dry place, away from light

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

Do not take this medicine if you notice any visible signs of deterioration.

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. Further information

• What Ipiclav-625 Tablets

Active ingredient:

Each film-coated tablet contains:

Amoxicillin Trihydrate BP equivalent to Amoxicillin 500 mg

Potassium Clavulanate equivalent to Clavulanic Acid 125 mg

Inactive ingredients:

Colloidal Silicon Dioxide BP, Croscarmellose Sodium BP, Microcrystalline Cellulose BP, Magnesium Stearate BP, Hydroxy Propyl Methyl Cellulose BP, Dibutyl Phthalate BP, Purified Talc BP, Titanium Dioxide BP, Isopropyl Alcohol BP, Methylene Chloride USNF.

• What product look like and contents of the pack

- White to off white , oval shaped, biconvex film coated tablets.
- Strip of 3 Tablets packed in a showbox along with a leaflet

• Name and address of marketing authorization holder and manufacturer



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