

Patient Information Leaflet

Ipiclav-1g

Amoxicillin & Clavulanate Potassium Tablets USP

The information in this leaflet applies only to Ipiclav-1g 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-1g Tablet is and what it is used for

Ipiclav-1g 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-1g 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 Ipiclav-1g

Do not take Ipiclav-1g:

- if you are allergic to amoxicillin, clavulanic acid, penicillins 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 or throat.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take Ipiclav-1g if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ipiclav-1g Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ipiclav-1g 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-1g 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-1g, 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-1g. This is because Ipiclav-1g can affect the results of these types of tests.

Other medicines and Ipiclav-1g 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-1g, 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-1g.

If medicines to help stop blood clots (such as warfarin) are taken with Ipiclav-1g Tablets then extra blood tests may be needed.

Ipiclav-1g can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Ipiclav-1g 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.

Driving and using machines

Ipiclav-1g can have side effects 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-1g

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

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with another formulation such as oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Ipiclav-1g tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

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-1g Tablets

- Take with a meal
- Swallow the tablets whole with a glass of water.
- Do not take Ipiclav-1g for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Ipiclav-1g Tablets than you should

If you take too much Ipiclav-1g, 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-1g 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 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ipiclav-1g Tablets

Keep taking Ipiclav-1g 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.

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

Warning: Allergic reactions can sometimes occur delayed.

Contact a doctor immediately if you get any of these symptoms. Stop taking Ipiclav-1g Tablets.

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

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 Ipiclav-1g with a meal

- 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 your 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 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.

- Allergic reactions
- Inflammation of the large intestine
- 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))
 - Inflammation of the protective membrane surrounding the brain (aseptic meningitis)

Contact a doctor immediately if you get 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 skin and whites of eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Ipiclav-1g 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.

5. How to store Ipiclav-1g

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

Store below 30°C, in a dry place

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-1g Tablets

Active ingredient:

Each film-coated tablet contains:

Amoxicillin Trihydrate USP equivalent to Amoxicillin 875 mg

Potassium Clavulanate equivalent to Clavulanic Acid 125 mg

Inactive ingredients:

Colloidal SiliconDioxide(Aerosil-200), Croscarmellose Sodium, Microcrystalline cellulose(Avicel pH 200), MagnesiumStearate (Veg Grade), HydroxyPropylmethyl cellulose(HPMC-15CPS), Dibutyl phthalate, Purifiedtalco, Titaniumdioxide, Isopropyl Alcohol, Methylenechloride.

• What product look like and contents of the pack

White to off white , oval shaped film coated tablets with 'R1' embossed on one side and plain on other side.

Strip of 2& 3 tablets packed in a showbox along with a leaflet

• Name and address of marketing authorization holder and manufacturer



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