

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Pinaclav 500mg/125mg Tablets amoxicillin and clavulanic acid**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or your child). Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Pinaclav is and what it is used for
2. Before you take Pinaclav
3. How to take Pinaclav
4. Possible side effects
5. How to store Pinaclav
6. Further information

**1. WHAT PINACLAV IS AND WHAT IT IS USED FOR**

Pinaclav 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.

Pinaclav is used in adults and children to treat the following infections:

500 mg/125 mg tablets

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

**2. BEFORE YOU TAKE PINACLAV**

**Do NOT take Pinaclav:**

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

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

**Take special care with Pinaclav**

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 Pinaclav.

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 Pinaclav or a different medicine.

### **Conditions you need to look out for**

Pinaclav 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 Pinaclav, 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 Pinaclav. This is because Pinaclav can affect the results of these types of tests.

### **Using other medicines**

Please tell your doctor or pharmacist if you are using or have recently used 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 Pinaclav, 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 Pinaclav.

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

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

Pinaclav can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

If you are a transplant patient taking mycophenolate mofetil talk to your doctor.

### **Pregnancy and breast-feeding**

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Pinaclav can have side effects and the symptoms may make you unfit to drive.

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

### **Important information about some of the ingredients of Pinaclav**

Pinaclav tablets contain:

- **Sucrose** (0.072mg per tablet) – if you know that you have an intolerance to some sugars, talk to your doctor before taking these tablets.

### **3. HOW TO TAKE PINACLAV**

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

#### **Adults and children weighing 40 kg and over**

500 mg/125 mg tablets

The usual dose is:

- 1 tablet three times a day

#### **Children weighing less than 40 kg**

Children aged 6 years or less should preferably be treated with Pinaclav oral suspension .

500 mg/125 mg tablets

Ask your doctor or pharmacist for advice when giving Pinaclav tablets to children weighing less than 40 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 Pinaclav**

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

#### **If you take more Pinaclav than you should**

If you take too much Pinaclav, 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 Pinaclav**

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.

#### **If you stop taking Pinaclav**

Keep taking Pinaclav 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 product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Pinaclav 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 mouth (*angioedema*), causing difficulty in breathing
- collapse.

→ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Pinaclav.**

### **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 Pinaclav before food

- 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.

### **Other side effects**

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

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the membranes 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 (*exanthemous pustulosis*).

→ 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 the eyes appear yellow
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Pinaclav or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Te; +353 1 676 4971; Website: [www.hpra.ie](http://www.hpra.ie) ; e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE PINACLAV**

Keep out of the sight and reach of children. Do not use Pinaclav after the expiry date ('EXP') shown on the label and outer carton. Do not store the product above 25°C.

Glass bottles: keep the container tightly closed in order to protect from moisture.

Blisters: store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Pinaclav contains**

The **active ingredients** are amoxicillin and clavulanic acid; each tablet contains 500mg amoxicillin (as amoxicillin trihydrate) and 125mg clavulanic acid (as potassium clavulanate).

The **other ingredients** are microcrystalline cellulose, quinoline yellow (E104), titanium dioxide (E171), crospovidone, povidone, colloidal anhydrous silica, stearic acid, macrogol 6000, hypromellose, sodium saccharin, magnesium stearate, vanilla flavour (contains sucrose) - *For additional information on Sucrose see end of Section 2 “Important information about some of the ingredients”.*

### **What Pinaclav looks like and contents of the pack**

These tablets are yellowish-white or light yellow oblong-formed, biconvex tablet with “625” marked on one side and an engraved line on the reverse. They are supplied in either amber glass bottles of 5 or 15 tablets or aluminium blister strips of 15 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary. PA 281/93/3

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### **Advice/medical education**

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.