

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pinaclav 125mg/31.25mg per 5ml, powder for oral suspension amoxicillin and clavulanic acid

Read all of this leaflet carefully before you start giving your child 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- 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.

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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 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. BEFORE YOU GIVE PINACLAV

Do NOT give your child Pinaclav:

- if they are allergic (hypersensitive) to amoxicillin, clavulanic acid or any of the other ingredients of Pinaclav (listed in section 6)
- if they 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 they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→Do not give Pinaclav to your child if any of the above apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Pinaclav.

Take special care with Pinaclav

Check with their doctor or pharmacist before giving your child this medicine if they:

- 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 your child, talk to their doctor or pharmacist before giving Pinaclav.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child 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 your child is 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 your child is 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 they 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 your child is taking or has recently taken any other medicines.

This includes medicines that can be bought without a prescription and herbal medicines.

If your child is taking allopurinol (used for gout) with Pinaclav, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the 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 your child who is about to take this medicine is pregnant or breast-feeding, please tell your doctor or pharmacist.

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

Important information about some of the ingredients of Pinaclav

Pinaclav oral suspension contains:

- Sucrose (0.1mg per 5ml) – if you know your child has an intolerance to some sugars, talk to your doctor before giving this medicine.

- Sodium – this medicine contains 2 mmoles of sodium per 5ml dose, which must be taken into consideration by children on a controlled sodium diet.
- Pinaclav contains Aspartame E951 (2.5mg per 5ml) – which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

3. HOW TO GIVE PINACLAV

Always give Pinaclav 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 or over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you how much Pinaclav you should give to your baby or child
- Usual dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.
- You may be provided with a plastic measuring spoon or measuring cup. You should use this to give the correct dose to your baby or child.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Pinaclav

- Always shake the bottle well before each dose
- Give 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 give your child Pinaclav for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Pinaclav than you should

If you give your child too much Pinaclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Pinaclav

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose.

If your child stops taking Pinaclav

Keep giving your child Pinaclav until the treatment is finished, even if they feel better. Your child needs 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. 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 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 your child gets 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 your child gets 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 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 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 your child gets 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 child's 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 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 ; e-mail: 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.

To the patient: Do not use Pinaclav after the expiry date ('EXP') shown on the label. This product should be stored in the refrigerator at 2-8°C and used within 7 days. Do not freeze.

To the pharmacist: Keep the bottle tightly closed in order to protect from moisture. Do not store above 25°C. Do not use Pinaclav after the expiry date ('EXP') shown on the label.

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 5ml of suspension contains 125mg amoxicillin (as amoxicillin trihydrate) and 31.25mg clavulanic acid (as potassium clavulanate).

The **other ingredients** are silicon dioxide, microcrystalline cellulose, colloidal anhydrous silica, xanthan gum (E415), monosodium citrate, sodium citrate, aspartame (E951), sodium saccharin, milk flavour, orange flavour, vanilla flavour (contains sucrose) - *For additional information on some ingredients see end of Section 2 "Important information about some of the ingredients"*.

What Pinaclav looks like and contents of the pack

Pinaclav is a white to off-white powder for oral suspension with orange/vanilla smell. When reconstituted with water by the pharmacist, the medicine is available as a bottle containing 100 ml of suspension.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary.
PA 281/93/1

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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.