

MYCLAV

(Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

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What is Myclav Powder for Oral Suspension used for

Myclav is an antibiotic used in children to treat infections in different parts of the body caused by bacteria in respiratory tract, urinary tract, skin and soft tissue and dental infections.

How Myclav Powder for Oral Suspension works

Myclav contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin is a penicillin antibiotic. Amoxicillin can sometimes be stopped from working (made inactive). The other active medicine, clavulanic acid, stops this from happening.

Before you use Myclav Powder for Oral Suspension

-When you must not use it

Do not use this medicine if:

- Your child is allergic (hypersensitive) to amoxicillin, clavulanic acid, other penicillin

based antibiotics, or similar antibiotics called cephalosporins

Your child has ever had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking an antibiotic.

- If you think any of these apply to your child, check with your doctor before you take Myclav.

-Before you start to use it

Take special care and get advice from your doctor if:

- Your child has ever had an allergic reaction to any other antibiotics or medicines. This might include a skin rash or swelling of the face or neck.
- Your child has glandular fever (mononucleosis)
- Your child is taking medicines, such as warfarin, that are used to prevent blood clots
- Your child has liver problems
- Your child has kidney disease
- Your child is not urinating regularly or not able to drink very much
- Your child has a genetic condition called phenylketonuria

Check with your doctor if you think any of these may apply to your child. Your doctor will decide whether Myclav is suitable for your child and may need to adjust the dose or give your child a different medicine.

-Taking other medications

Tell your doctor or pharmacist if your child is taking any other medicines, if your child has taken any recently, or if your child starts taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how Myclav works, or make it more

likely that your child will have side effects. These include:

- Probenecid and allopurinol (used to treat gout)
- Anticoagulants (used to prevent blood clots) such as warfarin and acenocoumarol
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs)

Tell your doctor or pharmacist if your child is taking any of these.

How to use Myclav Powder for Oral Suspension

Tap bottle gently until all the powder flows freely. Add water up to 70 ml dilution mark which is shown on the label affixed to the Bottle. Replace the cap and shake the bottle until all the powder is suspended. Add more water until the level of the fill lines is attained and shake again. When first reconstituted, allow to stand for 5 minutes to ensure full dispersion.

-How much to use

Always take Myclav exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you're not sure. Your doctor will decide on the correct dosage for your child.

- Shake the bottle well before taking each dose.
- A dosing syringe, spoon or cup may be supplied with the pack, which you can use to measure the dose accurately.
- A dosing syringe should be used to give the correct dose to children below 3 months.

Patients with kidney or liver problems

- If your child has kidney problems, your doctor may give you a different strength or a different medicine.

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• If your child has liver problems, you may have more frequent blood tests to check how your child liver is working.

-When to use it

Take Myclav at the start of a meal or slightly before.

-How long to use it

It is important that your child takes the full course of Myclav. Don't stop unless your doctor advises you to – even if your child is feeling better. If your child doesn't complete the full course of treatment, the infection may come back.

Do not take Myclav for more than 14 days. If your child still feel unwell you should go back to see your doctor.

-If you forget to use it

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember. If you're not sure what to do, ask your doctor or pharmacist.

-If you use too much (overdose)

If your child accidentally takes too much Myclav, it is unlikely to cause any serious problems. The most common side effects of taking too much Myclav are nausea, vomiting and diarrhoea.

If you're worried, or your child feels unwell: Ask your doctor or pharmacist for advice.

While you are using it

-Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

-Things you must not do

This medicine has been prescribed for your child, and you should not

pass it on to other. It may harm them, even if their symptoms are the same as your child's.

-Things to be careful of

Take special care and get advice from your doctor if:

- Your child develops a skin rash while taking Myclav

- Do not give any more suspension and tell the doctor at once

Myclav suspension contains aspartame, which is a source of phenylalanine. If your child has an intolerance to aspartame or has a condition called phenylketonuria (PKU), check with your doctor that Myclav is right for your child.

Side effects

Like all medicines, Myclav can cause side effects, but not everybody gets them.

Myclav may cause severe allergy and serious skin reactions. Stop using Myclav and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking Myclav. Signs include:

- raised, itchy rash (hives)
- 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), which may cause difficulty in swallowing or breathing
- collapse.
- chest pain which can be a sign of a potentially serious allergic reaction called *Kounis syndrome*.

Get medical help immediately if you get any of these symptoms. Stop taking Myclav.

Serious skin reactions

These are rare in people taking Myclav. Signs include: 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*).

These are very rare in people taking Myclav. Signs include:

- 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 blisters and peeling skin on much of the body surface (*toxic epidermal necrolysis*)
 - a widespread, red, skin rash with small blisters containing pus (*exanthematous pustulosis*)
 - a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)
- Get medical help immediately if you get any of these symptoms. Stop taking Myclav.

Stop taking Myclav and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Serious liver problems

On rare occasions, medicines like Myclav can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

Tell your doctor as soon as possible if you get any of these symptoms.

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Severe diarrhoea

(*Pseudomembranous colitis*)

On rare occasions, medicines like Myclav can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever. Tell your doctor as soon as possible if you get any of 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 (fungal infection caused by *Candida* in the vagina, mouth or skin folds)
- feeling sick (nausea)
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people:

- dizziness
- headache
- indigestion
- skin rash
- itching
- itchy, bumpy rash (hives)

Uncommon side effects that may show up in blood tests are:

- increase in some substances (enzymes) produced by the Liver

Rare side effects

These may affect up to 1 in 1,000 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*)

Rare side effects that may show up in blood tests are:

- decrease in the number of white blood cells (*leucopenia*, including *neutropenia*)
- decrease in the number of cells that help blood to clot (*thrombocytopenia*)

Very rare side effects

These may affect up to 1 in 10,000 people:

- severe allergic reactions
- serious skin reactions
- inflammation of the liver (*hepatitis*)
- yellowing of the whites of the eyes or skin (*jaundice*)
- inflammation of the large intestines
- inflammation of the kidney (*nephritis*)
- an increase in the time blood takes to clot

• being unusually active

(*hyperactivity*)

- fits (*seizures*)
- black tongue which looks hairy
- inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- stained teeth that can usually be removed by brushing

Very rare side effects that may show up in blood or urine tests are:

- severe decrease in the number of white blood cells (*agranulocytosis*)
- red blood cells destroyed too quickly (*haemolytic anaemia*)
- crystals in urine

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Myclav Powder for Oral Suspension

-Storage

The dry powder should be stored in unopened containers in a dry place at below 30°C. **Once reconstituted, suspension must be stored in refrigerator (2°C - 8°C), do not**

freeze and should be used within 7 days.

Keep all medicines out of reach of children.

-Disposal

Don't dispose of medicines in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

-What it looks like

White to off- white free flowing powder, which on reconstitution gives white to off- white coloured liquid suspension.

Flavour: Raspberry and Orange flavour

-Ingredients

Active ingredient(s): Amoxicillin Trihydrate equivalent to Amoxicillin & Potassium Clavulanate, diluted equivalent to Clavulanic acid.

Inactive ingredient(s): Silicon dioxide, xanthan gum, hypromellose, colloidal anhydrous silica, succinic acid, aspartame, orange flavour, raspberry flavour.

-MAL number

Myclav (Amoxicillin & Clavulanate Potassium for Oral Suspension USP 228.5mg/5ml): MAL24086015AZ

Manufacturer

UNICHEM LABORATORIES LTD.
Village Bhatauli Kalan, Baddi, Dist. Solan (H.P.) – 173 205, India.

Product Registration Holder

HEALOL PHARMACEUTICALS SDN BHD.
No. 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, Malaysia.

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