

MYCLAV 625 TABLET

Consumer Medication Information Leaflet (RiMUP)

Amoxicillin & Clavulanate Potassium Tablets USP 625 mg

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What Myclav 625 Tablet is used for

Myclav is used for treatment of infections caused by susceptible strains of the designated organisms. Myclav 625 Tablet is used to treat following infections:

- Respiratory Tract infection
- Urinary Tract infections
- Skin and soft tissue infections
- GI tract infections
- Bone and joint infection
- Dental infections
- other infections etc.

How Myclav 625 Tablet works

Myclav 625 Tablet is an antibiotic combination of amoxicillin and clavulanic acid. The clavulanate anticipates defence mechanism by blocking the β lactamase enzymes, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body. Clavulanate by itself has little antibacterial activity; however in association with amoxicillin it produces an antibiotic agent of broad spectrum.

Before you use Myclav 625 Tablet

- When you must not use it

If you are penicillin allergic or with suspected glandular fever or pharyngitis or contraindicated in patients with previous history of amoxicillin/Clavulanate potassium associated cholestatic jaundice/ hepatic dysfunction.

- Before you start to use it

1. You should talk to your doctor if you had previous hypersensitivity reactions to Penicillins, Cephalosporins or other allergens.

2. You should use with caution if you are with evidence of hepatic dysfunction.

3. Periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is advisable during prolonged therapy.

- Taking other medicines

Tell your doctor or pharmacist if you are using:

1. Probenecid: It decreases the renal tubular secretion of Amoxicillin. Concurrent use with Amoxicillin, Clavulanate potassium may result in increased and prolonged blood levels of amoxicillin. Co-administration of probenecid cannot be recommended.

2. Oral Contraceptives:

Amoxicillin/Potassium Clavulanate may reduce the efficacy of oral contraceptives.

How to use Myclav 625 Tablet

- How much to use

For Treatment of infection

Adult and children over 12 years: 1 tablet two times daily

Severe infections: 1 tablet three times daily.

For renal impairment: one 625mg tablet 12 hourly.

- When to use it

It is oral tablet. To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of Myclav is optimised when taken at the start of a meal.

- How long to use it

Therapy should be appropriate to the indication and should not exceed 14 days without review.

- If you forget to use it

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. Ask your doctor or pharmacist.

- If you use too much (overdose)

In case of overdose discontinue medication, treat symptomatically and institute supportive measures as required. Interstitial nephritis resulting in oliguric renal failure may occur after overdosage with amoxicillin. Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and Clavulanic acid.

While you are using it

- Things you must do

Periodic assessment of organ system functions, including renal, hepatic and hematopoietic function, is advisable during prolonged therapy.

If super infections occur (usually involving *Pseudomonas* or *Candida*), Myclav 625 Tablet should be discontinued and/or appropriate therapy instituted.

- Things you must not do

If you are penicillin allergy, you should not have Myclav 625 Tablet, as the Amoxicillin component is likely to precipitate a hypersensitivity reaction.

If you are suspected glandular fever, or pharyngitis, you should not have Amoxicillin/clavulanic acid.

- Things to be careful of

You should discuss with doctor if you had any previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens.

Side effects

Stop taking Myclav 625 Tablet 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.

-Additionally the adverse drug reaction with amoxicillin/ Clavulanic acid are diarrhea/loose stools, nausea, skin rashes and urticarial, vomiting and vaginitis. The overall incidence of side effects and in particular diarrhea, increased with the higher recommended dose.

Myclav 625 Tablet may cause severe allergy and serious skin reactions.

Stop using Myclav 625 Tablet and seek medical assistance immediately if you experience any of the following symptoms:

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

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

Storage and Disposal of Myclav 625 Tablet

- Storage

Store below 30° C.

- Disposal

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.

Product Description

- What it looks like

White, film coated, oval shaped, plain biconvex tablets.

- Ingredients

- Active ingredient(s)
Amoxicillin Trihydrate USP
equivalent to Amoxicillin
Clavulanate Potassium USP
equivalent to Clavulanic acid
- Inactive ingredients
Magnesium Stearate BP
Sodium Starch Glycolate BP
Colloidal Anhydrous Silica BP

Microcrystalline Cellulose BP
Sodium Lauryl Sulphate BP
Opadry OY-C-7000A O.sp
Methanol BP
Dichloromethane Ph.Eur

- MAL number(s):

MAL09111726AZ

Manufacturer

Unichem Laboratories Limited

Village Bhatauli Kalan, Baddi, Dist – Solan (H.P.) - 173205.India.

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd.

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