

## PROPOSED CLEAN PACKAGE INSERT

hevid



### Clamovid

VICLA22-var (SIN)

#### Description

Clamovid 625 Tablet - Oblong, white, film-coated tablet with shallow convex faces

Clamovid Granules - White to yellowish granules

#### Composition

Clamovid 625 Tablet - Amoxicillin (as trihydrate) 500 mg/tablet  
Clavulanic Acid (as potassium clavulanate) 125mg/tablet

Clamovid Granules - Amoxicillin (as trihydrate) 125mg/5ml  
Clavulanic Acid (as potassium clavulanate) 31.25mg/5ml

#### Actions and Pharmacology

Amoxicillin is a broad-spectrum bactericidal antibiotic which exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell wall synthesis. Clavulanic acid by itself has little antibacterial activity. However, in combination with amoxicillin, it extends the spectrum of amoxicillin to cover a wider range of organisms, including many resistant to other beta-lactam antibiotics.

Oral absorption of Clamovid is optimized at the start of a meal. The presence of food does not appear to diminish the total amount absorbed. Amoxicillin is widely distributed in body tissues and fluids. It crosses the placenta and small amounts are excreted in breast milk. Amoxicillin is metabolized to a limited extent to penicilloic acid whilst clavulanic acid may be metabolized more extensively than amoxicillin. Excretion is mainly via renal and biliary systems.

#### Indications

For treatment of acute otitis media, sinusitis, pneumonia, skin and soft tissue infections, urinary tract infections caused by betalactamase-producing strains of bacteria.

#### Contraindications

- Contraindicated in patients known to be hypersensitive to penicillin. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics e.g. cephalosporins.
- Contraindicated in patients with a previous history of penicillin-associated jaundice/hepatic dysfunction
- Contraindicated in patients with infectious mononucleosis

#### Precautions/warnings

- Patients sensitive to one penicillin may be allergic to other penicillins or related antibiotics such as cephalosporins, cephamycins or penicillamine
- Caution in patients with history of allergy such as asthma, eczema, hay fever or hives.

- Caution patients with a history of bleeding disorders.
- Caution in patients with a history of gastrointestinal disease especially ulcerative colitis, regional enteritis or antibiotic associated colitis.
- Caution in patients with impaired renal function. Adjustment of dosage may be necessary.
- Use with caution in patients with hepatic dysfunction as changes in liver function tests have been observed.
- Erythematous rashes have been associated with glandular fever in patients receiving amoxicillin.
- Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.
- Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, Clamovid must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management (including intubation) may also be required.

#### Use in Pregnancy and Lactation

- Use should be avoided in pregnancy, especially in the first trimester, unless considered essential by the physician.
- Clamovid may be administered during the period of lactation. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

#### Side/adverse Effects

Side effects are uncommon and mainly of a mild and transitory nature.

- Gastrointestinal effects : Diarrhoea, indigestion, nausea, vomiting and mucocutaneous candidiasis have been reported.  
Taking Clamovid at the start of meals may reduce them.
- Genito-urinary effects : Vaginal itching, soreness and discharge
- CNS effects : Convulsions may occur with impaired renal function or in those receiving high doses.
- Hepatic effects : Moderate and symptomatic rises in AST and / or ALT and alkaline phosphatase have been reported occasionally. Hepatitis and cholestatic jaundice have been reported rarely. These hepatic reactions have been reported more commonly with Clamovid than with other penicillins.
- Nervous system disorders : Very rare: Aseptic meningitis



- Hypersensitivity reactions : Urticarial and erythematous rashes sometimes occurs. Rarely erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, serum sickness-like syndrome and hypersensitivity vasculitis have been reported. Very rare: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Treatment should be discontinued if one of these disorders occurs.
- Haematology effects : As with other beta-lactams, transient leucopenia, thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of time and prothrombin time has also been reported rarely.

### Drug Interactions

- Concurrent use of Clamovid with anticoagulants may cause prolongation of bleeding time and prothrombin time. Patients should be monitored carefully for signs of bleeding.
- Clamovid may reduce the efficacy of oral contraceptives. An alternate or additional method of contraception should be used while taking Clamovid.
- Concomitant use of Clamovid with allopurinol can increase the likelihood of allergic reactions, especially in hyperuricaemic patients.
- Concurrent use with probenecid will decrease renal tubular excretion of amoxycillin and this requires careful monitoring.
- Bacteriostatic antibiotics such as chloramphenicol, erythromycins, sulphonamides and tetracyclines may infect with the bacterial effect of Clamovid.

### Overdosage

Clinical features : Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.

### Treatment for overdosage

Since there is no specific antidote, overdosage may be treated symptomatically with attention to the water electrolyte balance. Clamovid may be removed from the circulation by haemodialysis.

### Dosage and Administration

#### CLAMOVID 625 TABLET

##### Adults and Children Over 12 years old:

Severe infections : Oral, one tablet, three times a day.  
Other infections : Oral, one tablet, two times a day.

#### Dosage in Renal Impairment:

Adults : Mild impairment (Creatinine clearance > 30ml/min):  
No change in dosage.  
Moderate impairment (Creatinine clearance 10-30 ml/min):  
One tablet, 12 hourly.  
Severe impairment (Creatinine clearance < 10ml/min):  
Not recommended.

#### Dosage in Hepatic Impairment:

Dose with caution; monitor hepatic function at regular intervals. There are, as yet, insufficient data on which to base a dosage recommendation.

Note: Not recommended in children of 12 years and under.

#### CLAMOVID GRANULES

The usual recommended daily dosage is 25 mg/Kg/day in divided doses every 8 hours. In more serious infections the dosage may be increased up to 50 mg/Kg/day in divided doses every eight hours.

#### Children:

1 to 6 years (10 to 18kg) : Oral, 5ml (approximately 125mg of Amoxycillin and 31.25mg of Clavulanic Acid every eight hour.  
7 to 12 hours (18 to 40kg) : Oral, 10ml (approximately 250mg of Amoxycillin and 62.5mg of Clavulanic Acid) every eight hours.

**Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.**

Storage : Store below 25°C. Protect from light and moisture.  
Presentation/Packing : Tablet 625mg x alu-alu blisters of 3 x 5's, 2 x 5's  
Granules 156.25mg/5ml x amber glass bottles of 100ml

#### Contract Manufactured for Hovid Bhd.

121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),  
30010 Ipoh, Perak, Malaysia.

by: Bilim Ilaç Sanayi ve Ticaret Anonim Şirketi

Çerkezköy Organize Sanayi Bölgesi, Karaağaç,  
Mh. 5. Sk. No: 6, Kapaklı – Tekirdağ 59510, Turkey.

Revision date : April 2022

12024320

