

CLAMOVID BID FORTE GRANULES

Amoxicillin Trihydrate / Potassium Clavulanate (457 mg/5 ml)

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What Clamovid BID Forte is used for

Clamovid BID Forte is used to treat bacterial infections such as infections of the ear and sinus, respiratory tract, urinary tract, skin and soft tissue.

How Clamovid BID Forte works

Clamovid BID Forte contains two active ingredients amoxicillin and clavulanic acid, both are antibiotics that work by killing bacteria that cause the infections.

Before you use Clamovid BID Forte

- When you must not use it

Do not use this medicine if:

- Your child is allergic to amoxicillin, clavulanic acid, other penicillin-based antibiotics, similar antibiotics called cephalosporins or any other ingredients of this medicine (listed in Product Description)
- Your child has or had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking an antibiotic.
- Your child has infectious mononucleosis (a viral infection that causes fever, sore throat and swollen glands).

- Before you start to use it

Take special care and get advice from your doctor if your child:

- has liver or kidney problems.
- has history of diarrhea during or

after antibiotic therapy.

- has allergies such as asthma, eczema, hay fever or hives.
- has a history of bleeding disorders.
- has stomach or bowel problems, especially colitis (inflammation of the inner lining of the large intestine).

- Taking other medicines

Tell your doctor or pharmacist if your child is taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if your child is taking:

- Probenecid and allopurinol (used to treat gout)
- Blood thinning medications or medicines used to dissolve blood clots (thrombolytic agents)
- Oral contraceptives
- Other antibiotics such as chloramphenicol, erythromycin, sulphonamides or tetracyclines

How to use Clamovid BID Forte

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

To prepare, fill the bottle halfway with water. Put the cap back on and shake well until the powder is mixed. Let it sit for 5 minutes. Then add more water up to the 70 ml mark and shake again.

- How much to use

For mild to moderate infections:

- Children 2 to 6 years (13–21 kg):
½ teaspoonful (2.5 mL) twice daily
- Children 7 to 12 years (22–40 kg):
1 teaspoonful (5 mL) twice daily

For severe infections:

- Children 2 to 6 years (13–21 kg):
1 teaspoonful (5 mL) twice daily
- Children 7 to 12 years (22–40 kg):
2 teaspoonfuls (10 mL) twice daily

Take exactly as prescribed by your doctor. Use the measuring device provided to ensure the correct dose is given.

Child with kidney or liver problems

- If your child has kidney problems, your doctor may adjust the dose. This medicine is not recommended for children with severe kidney impairment.
- If your child has liver problems, your doctor may monitor your child's condition while taking this medicine.

- When to use it

Take twice a day or as directed by your doctor or pharmacist.

- How long to use it

It is important that your child takes the full course of Clamovid BID Forte. 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 Clamovid BID Forte for more than 14 days. If your child still feels unwell you should go back to see your doctor.

- If you forget to use it

Take the missing dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if your child or

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anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause upset stomach and loss of fluid and electrolyte from the body.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Clamovid BID Forte.

Take Clamovid BID Forte only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by the doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Clamovid BID Forte to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Clamovid BID Forte may cause severe allergic reactions. Symptoms may include skin rashes, fever, itchiness and breathing difficulties. If any of these happen, stop using the medication and seek medical attention immediately.

Long-term use may increase the risk of infections caused by other organisms that are not affected by this medicine.

Side Effects

Like all medicines, Clamovid BID Forte can cause side effects, but not everybody gets them.

Possible side effects are:

Gastrointestinal effects:

Diarrhoea, upset stomach, nausea, or vomiting. Some people may also get a yeast infection (such as in the mouth or skin). Taking Clamovid at the start of a meal may help reduce these effects.

Genitourinary effects

Vaginal itching, soreness and discharge.

Nervous system effects

Seizures (fits) may occur, especially in people with kidney problems or those taking high doses.

Hepatic effects

There may be mild changes in liver function tests, usually without symptoms. The risk may increase if the medicine is used for more than 14 days.

Hypersensitivity reactions

Allergic reactions such as skin rash, swelling (for example, of the face or lips), or severe reactions may occur. Stop taking the medicine and seek medical help if you notice these symptoms.

Blood disorders

Rarely, temporary changes in blood counts may occur, such as low white blood cells or platelets, or anaemia.

Severe skin reactions (very rare)

Serious skin reactions with rash, fever, and involvement of other organs may occur. Seek medical attention immediately if you develop unusual skin symptoms.

You may report any side effects of 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 Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Clamovid BID Forte

- Storage

- Keep out of the reach and sight of children
- Store in a dry place in the original packaging to protect from light and moisture.
- The dry powder should be stored in unopened container in a dry place below 30°C.
- Once made up, the suspension should be stored in a refrigerator (2°C to 8°C).
- Dispose of any unused suspension 7 days after first make up.

- Disposal

Do not dispose of medicines in wastewater 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

Creamy, white coloured homogenous powder. Reconstituted in water to form a suspension.

- Ingredients

- Active ingredient(s)

- Amoxicillin trihydrate
- Potassium clavulanate

- Inactive ingredients

- Sodium Benzoate
- Citric acid
- Xanthan Gum
- Essence Raspberry
- Sodium Citrate
- Colloidal Silicon Dioxide
- Microcrystalline Cellulose
- Silicon Dioxide
- Powdered Sucrose

- MAL Number:

MAL20033972ACZ

Manufacturer:

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BILIM ILAC SANAYI VE TICARET

A.S.

Karaagac Mah. 7, Sk. No: 7A,

Kapakli / Tekirdag 59510, Turkey.

Product Registration Holder

Hovid Bhd.

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