

PATIENT INFORMATION LEAFLET

Clamoxin - 156.25 Suspension

(Amoxicillin and Clavulanate Potassium for Oral Suspension USP 156.25 mg)

Read all of this leaflet carefully before you start taking this medicine:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Clamoxin - 156.25 Suspension is and what it is used for
2. Before you use Clamoxin - 156.25 Suspension
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1. What is Clamoxin - 156.25 Suspension and what it is used for

Clamoxin - 156.25 Suspension 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.

Clamoxin - 156.25 Suspension is used in babies and 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 use Clamoxin - 156.25 Suspension

Do not use Clamoxin - 156.25 Suspension for children:

- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- if they have ever had a severe allergic 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.

Take special care with Clamoxin - 156.25 Suspension

Check with their health care provider before giving your child this medicine if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

Taking other medicines

Tell the health care provider if your child is taking, has recently taken or might take 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 Clamoxin - 156.25 Suspension, 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 Clamoxin - 156.25 Suspension.

If medicines to help stop blood clots (such as warfarin) are taken with Clamoxin - 156.25 Suspension then extra blood tests may be needed.

Clamoxin - 156.25 Suspension can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Pregnancy, breast-feeding and fertility

If your child who is about to take this medicine is breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their health care provider for advice before taking this medicine.

Driving and using machines

Do not drive because Clamoxin - 156.25 Suspension can have side effects and the symptoms may make you unfit to drive.

Do not use any tools or machines unless you are feeling well.

3. How to take Clamoxin - 156.25 Suspension

Always give this medicine exactly as your health care provider has told you. Check with health care provider 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 health care provider for advice.

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

Your doctor will advise you how much Clamoxin - 156.25 Suspension you should give to your baby or child.

You may be provided with a measuring spoon or cup. You should use this to give the correct dose to your baby or child.

Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

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 Clamoxin - 156.25 Suspension

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 Clamoxin - 156.25 Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If more Clamoxin - 156.25 Suspension is given to you than recommended

If you give your child too much Clamoxin - 156.25 Suspension, 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 Clamoxin - 156.25 Suspension

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 Clamoxin - 156.25 Suspension

Keep giving your child Clamoxin - 156.25 Suspension 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 medicine, ask your health care provider.

4. Possible side effects of Clamoxin - 156.25 Suspension

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 Clamoxin - 156.25 Suspension.**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. How to store Clamoxin - 156.25 Suspension

- Keep this medicine out of the sight and reach of children.
- **Dry powder**
 - Store in the original package in order to protect from moisture.
 - Do not store above 25°C.
 - Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- **Liquid suspension**
 - Store in a refrigerator (2°C - 8°C). Do not freeze.

- Once made up, the suspension should be used within 7 days.
- 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

Contents of the pack and other information

What Clamoxin - 156.25 Suspension contains:

The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 125 mg amoxicillin and potassium clavulanate equivalent to 31.25 mg of clavulanic acid.

The other ingredients are;

Colloidal Silicon Dioxide, Methocel-E5 Premium, Aspartame, Succinic acid, Xanthan gum, , Orange dry powder, Golden Caramel, Pineapple dry powder.

What Clamoxin - 156.25 Suspension looks like and content of the pack:

Clamoxin - 156.25 Suspension is a white or almost white powder supplied in a HDPE bottle. Once made up, the bottle contains 100 ml of a white or almost white liquid mixture called a suspension.

Marketing Authorisation Holder:

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