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AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE 400 MG + 57 MG / 5 ML POWDER FOR ORAL SUSPENSION		172-3080.00

## **Package leaflet: Information for the patient**

### **Curam 400 mg + 57 mg / 5 ml Powder for Oral**

#### ***Suspension Amoxicillin/clavulanic acid***

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

#### **What is in this leaflet:**

1. What Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension is and what it is used for
2. What you need to know before you take Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension
3. How to take Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension
4. Possible side effects
5. How to store Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension
6. Contents of the pack and other information

**1. What Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension is and what it is used for** Curam 400 mg + 57 mg / 5 ml Powder for Oral 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.

Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension is used in adults 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.

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## 2. What you need to know before you give Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension

### Do not give your child Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension:

- 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.

**Do not give Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension to your child if any of the above apply to your child.** If you are not sure, talk to your doctor or pharmacist before giving Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension.

### Warnings and precautions]:

Talk to your doctor or pharmacist before giving your child this medicine if they:

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

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child may be given a different strength of Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension or a different medicine.

**Conditions you need to look out for** Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension, to reduce the risk of any problems. See '*Conditions you need to look out for*' in **Section 4**.

### Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension. This is because Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension can affect the results of these types of tests.

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**Other medicines and Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

If your child is taking **allopurinol** (used for gout) with Curam 400 mg + 57 mg / 5 ml Powder for Oral 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 your dose of Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension.

If medicines to help stop blood clots (such as **warfarin**) are taken with Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension then extra blood tests may be needed.

Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension can affect how **methotrexate** (a medicine used to treat cancer or rheumatic diseases) works.

Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension may affect how **mycophenolate mofetil** (a medicine used to prevent the rejection of transplanted organs) works.

**Pregnancy and breast-feeding:**

If your child who is about to take this medicine is pregnant or breast-feeding, thinks it may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension contains glucose and sorbitol. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine.

**3. How to give Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

Always give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist, if you are not sure.

**Adults and children weighing 40 kg and over**

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

**Children weighing less than 40 kg**

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

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- Your doctor will advise you how much Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension you should give to your baby or child.
- You may be provided with a plastic measuring spoon or syringe doser. You should use this to give the correct dose to your baby or child.
- Usual dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

#### **Patients with kidney and liver problems**

- If your child has kidney problems the dose might be changed. 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 check how their liver is working.

#### **How to give Curam 400 mg + 57 mg / 5 ml Powder for Oral 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 Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

#### **If you give more Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension than you should**

If you give your child too much Curam 400 mg + 57 mg / 5 ml Powder for Oral 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 Curam 400 mg + 57 mg / 5 ml Powder for Oral 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 Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

Keep giving your child Curam 400 mg + 57 mg / 5 ml Powder for Oral 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 doctor or pharmacist.

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#### 4. Possible side effects

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 Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension.**

##### Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

**Contact your doctor as soon as possible** for advice if your child gets these symptoms.

##### Very common side effects (may affect more than 1 in 10 people)

- diarrhoea (in adults).

##### Common side effects (may affect up to 1 in 10 people)

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses. If affected take Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension before food.
- vomiting
- diarrhoea (in children).

##### Uncommon side effects (may affect up to 1 in 100 people)

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

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

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- increase in some substances (*enzymes*) produced by the liver

**Rare side effects** (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*)
- if you notice any of these symptoms contact a doctor urgently.

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

- low number of cells involved in blood clotting
- low number of white blood cells

**Frequency not known** (frequency cannot be estimated from the available data)

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
  - 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 extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
  - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
  - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*)

**Contact a doctor immediately if your child gets any of these symptoms.**

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing

Side effects that may show up in blood or urine tests:

- severe reduction in the number of white blood cells

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- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

#### Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

Keep this medicine out of the sight and reach of children.

The reconstituted suspension should be stored in a refrigerator (2°-8° C) and used within 7 days. Keep in the original container.

Keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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.

### **6. Contents of the pack and other information**

#### **What Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension contains**

The active substances are amoxicillin and clavulanic acid.

1 ml reconstituted suspension (corresponding to 0.160 g powder) contains:

Amoxicillin trihydrate corresponding to 80 mg amoxicillin.

Potassium clavulanate corresponding to 11.4 mg clavulanic acid

Other ingredients are: Citric acid, Trisodium citrate, Aspartame (E951), Talc, Guar galactomannan, Silicon dioxide, Lemon flavouring (natural flavouring materials, nature-identical flavouring materials, dextrose, maltodextrin, butylated hydroxyanisole E320, sorbitol syrup E420, Acacia gum E414); Peach-apricot flavouring, (natural flavouring materials, nature-identical flavouring materials, maltodextrin, butylated hydroxyanisole E320, sorbitol syrup E420, Acacia gum E414); Orange flavouring (nature-identical flavouring materials, artificial flavouring substances, maltodextrin, alpha-tocopherol E 307).

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**What Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension looks like and contents of the pack**

The primary packaging materials consists of  
Amber glass bottle (type III), 60 ml, 120 ml respectively 150 ml.  
Screw closure with sealing membrane  
graduated syringe (5 ml) for 60 ml bottles (for pack sizes of 35 ml, 50 ml, 60 ml suspension)  
measuring spoon (5 ml) for 120 ml bottles (for pack sizes of 70 ml, 75 ml, 100 ml suspension) and  
150 ml bottles (for a pack size of 140 ml suspension)

Original packs for preparing of 35, 50, 60, 70, 75, 100 and 140 ml suspension.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Curam 400 mg + 57 mg / 5 ml Powder for Oral Suspension**

This leaflet was last revised in: August 2015

**Instructions for reconstitution**

At time of dispensing, the dry powder should be reconstituted to form an oral suspension, as detailed below:

After opening the bottle remove the membrane carefully and completely and discard before reconstituting the product. Fill the bottle with water to just below the mark on the label and shake well at once. Then add water exactly to the mark and shake vigorously again.

Shake the bottle well before every withdrawal.

31.9 ml of water is added in order to get 35 ml prepared oral suspension.

45.5 ml of water is added in order to get 50 ml prepared oral suspension.



54.6 ml of water is added in order to get 60 ml prepared oral suspension.

63.7 ml of water is added in order to get 70 ml prepared oral suspension.

68.3 ml of water is added in order to get 75 ml prepared oral suspension.

89.3 ml of water is added in order to get 100 ml prepared oral suspension.

125.0 ml of water is added in order to get 140 ml prepared oral suspension.