

**1. WHAT Curam 457 mg/ 5 ml powder for oral suspension IS AND WHAT IT IS USED FOR**

Curam 457 mg/ 5 ml powder for oral suspension is an antibiotic. It belongs to a group of antibiotics called penicillins. It is used to treat infections caused by certain bacteria which are sensitive to the combination of amoxicillin/clavulanic acid.

Curam 457 mg/ 5 ml powder for oral suspension is used to treat:

- Infections of the tonsils and sinuses
- Ear infections
- Chest infections such as bronchitis and pneumonia
- Infections of the bladder and kidneys
- Infections of the skin and layers just under the skin

**2. BEFORE YOU TAKE Curam 457 mg/ 5 ml powder for oral suspension****Do not take Curam 457 mg/ 5 ml powder for oral suspension if:**

- You are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillins, cephalosporins or to any of the other ingredients of this medicine (See Further Information in Section 6).
- You have severe liver disease or ever had any liver disease caused by amoxicillin/clavulanic acid.
- You have infectious mononucleosis or leukaemia: you may have a higher risk of skin reactions.

**Take special care with Curam 457 mg/ 5 ml powder for oral suspension:**

Tell your doctor before taking Curam 457 mg/ 5 ml powder for oral suspension if you have, or ever had:

- Liver disease or if you are aged above 60 years: your doctor may have to ask you for a blood sample to follow your liver function.
- Kidney disease: your doctor may have to adjust the dose.
- Severe allergies or asthma: you may have a higher risk of allergic reactions.
- A bladder catheter. If so, drink plenty of liquid to prevent the forming of crystals in your urine.
- Severe vomiting or diarrhoea: the absorption of the medicine may not be guaranteed.

This medicine can also alter the results of urine tests for sugar. If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used.

**Taking other medicines:**

Please tell your doctor or pharmacist, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines can cause problems if you take them with Curam 457 mg/ 5 ml powder for oral suspension.

**Take care with the following medicines:**

- Antibiotics such as macrolides, tetracyclines: the effect of Curam 457 mg/ 5 ml powder for oral suspension may be reduced.
- Probenecid: the levels of amoxicillin may be increased in your blood and bile.
- Allopurinol: you may have a higher risk of skin reactions.
- Methotrexate: the toxicity of methotrexate may be increased.
- Digoxin: the absorption of digoxin may be increased.
- Sulfasalazin: the blood levels of sulfasalazin may be decreased
- Anticoagulants (to prevent blood clotting) such as coumatin: the tendency to bleed may be increased.
- Contraceptive pills: there is a risk of contraceptive pills not working to their greatest effect
- Dialfrum should not be used together with Curam 457 mg/ 5 ml powder for oral suspension

**Taking Curam 457 mg/ 5 ml powder for oral suspension with food and drink:**

It is recommended that you take Curam 457 mg/ 5 ml powder for oral suspension at the start of meals to reduce any possible digestive discomfort.

**Pregnancy and breast-feeding:**

Data on approximately 560 exposed pregnancies indicate no adverse effects of amoxicillin/clavulanic acid on pregnancy or on the health of the foetus or newborn child. However, in one study in women with premature rupture of the amnion it has been reported that prophylactic treatment with amoxicillin/clavulanic acid can be associated with an increased risk of necrotising enterocolitis (inflammation of the intestine) in neonates. As a precautionary measure, amoxicillin/clavulanic acid should only be used during pregnancy if in the judgement of the physician the potential benefits outweigh the possible hazards.

This medicine is excreted in breast milk in small quantities, therefore diarrhoea and colonisation of the digestive mucosae by yeasts are possible in the suckled infant, so that in some cases it may be necessary to wean the infant.

**Driving and using machines:**

This medicine has no influence on the ability to drive and use machines. Curam 457 mg/5 ml powder for oral suspension may sometimes have side effects such as mental confusion, rarely dizziness and even less often convulsions that may impair the ability to drive a vehicle, to operate machines and/or to work safely.

**Important information about some of the ingredients of this medicine**

Curam 457 mg/5 ml powder for oral suspension contains the sweetener aspartame, a source of phenylalanine. This may be harmful for people with phenylketonuria.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. HOW TO TAKE Curam 457 mg/ 5 ml powder for oral suspension**

Always take Curam 457 mg/ 5 ml powder for oral suspension exactly as your doctor has told you. You should check with your doctor or pharmacist, if you are not sure.

To open the bottle, press the childproof top down and then turn it. 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.

Your doctor will tell you the exact dose (in millilitres) you should take each day.

The usual dose for children aged 2 months to 12 years is:

- Infections of the skin: 25/3.6 mg/kg per day in two doses
- Ear infections and chest infections: 45/6.4 mg/kg per day in two doses

The dose is measured using the 5 ml measuring syringe which is provided with this medicine:

1. Put the adapter into the neck of the bottle
2. Put the end of the syringe into the adapter.
3. Turn the bottle upside down and slowly pull the plunger of the syringe until the appropriate amount of millilitres (see table below) is present in the tube.
4. Turn the bottle upright, remove the measuring syringe, leave the bottle adapter on the bottle and close the bottle.

Body Weight (kg)	25/3.6 mg/kg/day (ml twice daily)	45/6.4 mg/kg/day (ml twice daily)
3	0,5	0,8
4	0,6	1,1
5	0,8	1,4
6	0,9	1,7
7	1,1	2,0
8	1,3	2,3
9	1,4	2,5
10	1,6	2,8
11	1,7	3,1
12	1,9	3,4
13	2,0	3,7
14	2,2	3,9
15	2,3	4,2
16	2,5	4,5
17-21	2,5	5,0
22-29	4,0	7,5
30-40	5,0	10,0

Your doctor will tell you how long you will need to keep taking your medicine. Treatment should not last for more than 14 days without control by your doctor.

**People with liver disease**

Your doctor may have to ask you for a blood sample to follow your liver function.

**People with kidney disease**

Your doctor may have to lower the dose.

**If you take more Curam 457 mg/ 5 ml powder for oral suspension than you should:**

If you take too much of this medicine (overdose), talk to your doctor or go to a hospital straight away, and show them the pack. The most likely signs of overdose are: nausea, vomiting, diarrhoea, abdominal pain, convulsions (fits).

**If you forget to take Curam 457 mg/ 5 ml powder for oral suspension:**

If you forget to take your dose of this medicine, take the forgotten dose as soon as you remember. But do not give the next dose too soon, it must be at minimum 4 hours between two doses. Try to carry on as before (after 12 hours give the next dose). Do not take a double dose to make up for forgotten individual doses.

**If you stop taking Curam 457 mg/ 5 ml powder for oral suspension:**

Always keep taking this medicine until the course is finished, even if you feel better. If you stop taking this medicine too soon, the infection may come back. Also, the bacteria may become resistant to the medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Curam 457 mg/ 5 ml powder for oral suspension can cause side effects, although not everybody gets them.

**If you notice any of the following serious side effects, talk to your doctor immediately or go to a hospital straight away:**

Following serious side-effects are **rare** (affect less than 1 out of 1000 people):

- Sudden difficulty in breathing, speaking and swallowing
- Painful swelling of lips, tongue, face or neck
- Extreme dizziness or collapse
- Severe or itchy skin rashes, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs
- Diarrhoea that is serious, lasts a long time or has blood in it: This can be a sign of serious bowel inflammation.

Following side-effects are **very rare** (affect less than 1 out of 10,000 people):

- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler: This is a sign of liver problems.

**Other possible side-effects during treatment:**

Following side-effects are **common** (affect less than 1 out of 10 people):

- Nausea, vomiting, diarrhoea or soft stools. These effects are mostly mild and disappear during treatment or very soon after completion of therapy.
- Anal itching.
- "Fifth day" skin rash, which resembles measles.

Following side-effects are **uncommon** (affect less than 1 out of 100 people):

- Superinfections caused by resistant germs or yeasts.
- Vaginal itching and discharge.

Following side-effects are **rare** (affect less than 1 out of 1,000 people):

- Increase in blood platelets (thrombocytosis), abnormal breakdown of red blood cells (haemolytic anaemia).
- Allergic skin reactions (urticaria, purpura).
- Drug fever.
- Dizziness, headache, convulsions, aseptic meningitis.
- Yeast infections (candidiasis).
- Superficial tooth discoloration. The discoloration can be removed by teeth brushing.
- Moderate rise in liver enzymes.

Following side-effects are **very rare** (affect less than 1 out of 10,000 people):

- Changes in blood count (decrease of red or white blood cells and of platelets), prolongation of bleeding time. These manifestations are reversible after stopping the treatment.
- Hyperactivity, anxiety, sleeplessness, mental confusion, aggression.
- Black tongue.
- Hepatitis and cholestatic jaundice. Signs usually appear during or shortly after treatment, but in some cases they may appear only some weeks after treatment has been stopped.
- Inflammation of the kidneys (interstitial nephritis), crystals in the urine (crystalluria).

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

**5. HOW TO STORE Curam 457 mg/ 5 ml powder for oral suspension****Keep out of the reach and sight of children.**

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

Powder for preparing a suspension for oral use: Do not store above 30°C. Keep the container in the outer carton.

Do not use Curam 457 mg/ 5 ml powder for oral suspension after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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****What Curam 457 mg/ 5 ml powder for oral suspension contains**

The active substances are amoxicillin and clavulanic acid.

5 ml reconstituted suspension contains:

Amoxicillin trihydrate, corresponding to 400 mg amoxicillin.  
Potassium clavulanate, corresponding to 57 mg clavulanic acid.  
Other ingredients are: Citric acid, trisodium citrate, aspartame (E951), talc, Gaur galactomannan, silicon dioxide, lemon flavouring, peach-apricot flavouring, orange flavouring.

**What Curam 457 mg/ 5 ml powder for oral suspension looks like and contents of the pack**

Curam 457 mg/ 5 ml powder for oral suspension is available in original packs of 1 bottle, containing 11,8 g powder for preparing 70 ml suspension for oral use + 1 graduated syringe (5 ml).

**Marketing Authorisation Holder and Manufacturer**

Sandoz GmbH, Kundl – Austria

This leaflet is last approved in: 08/2006