

CAVUMOX SYRUP

Amoxicillin trihydrate / Clavulanic Acid (125 mg / 31.25 mg per 5 mL)

What is in this leaflet

1. What CAVUMOX SYRUP is used for
2. How CAVUMOX SYRUP works
3. Before you use CAVUMOX SYRUP
4. How to use CAVUMOX SYRUP
5. While you are using it
6. Side effects
7. Storage and disposal of CAVUMOX SYRUP
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What CAVUMOX SYRUP is used for

CAVUMOX SYRUP is used to treat bacterial infection in the middle ear and sinus, respiratory tract, urinary tract, skin and soft tissue and other infections in the bone and joints, and after surgical procedures.

How CAVUMOX SYRUP works

CAVUMOX SYRUP contains two active ingredients which are amoxicillin and clavulanate acid. Both are antibiotics that work by killing bacteria causing the infections.

Before you use CAVUMOX SYRUP

- When you must not take it
Do not take this medicine if:
 - your child are allergic or ever had severe allergic reactions to amoxicillin, clavulanate, other penicillin-based antibiotics, cephalosporins or similar antibiotics or any other ingredients of this medicine (listed in Product Description).
 - if your child have or had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking an antibiotic.
- Before you start to take it
Tell your doctor if your child:
 - Has phenylketonuria as this product contains aspartame
 - has liver or kidney problems
 - are not urinating regularly

- has history of diarrhea during or after antibiotic therapy

In some cases, your doctor may investigate the type of bacteria that is causing the infection. Depending on the results, you may be given a different strength or a different medicine.

- Taking other medicines

You should tell your doctor if your child are taking any of the following medicine:

- probenecid and allopurinol (used for gout)
- blood thinning medications (such as warfarin)
- mycophenolate mofetil (used to prevent rejection after organ transplants)

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

How to use CAVUMOX SYRUP

- How much to take
CAVUMOX SYRUP is only for children up to 12 years old.

The dosage will be determined by your doctor according to your child's body weight and the severity of the infections.

In general, the dosing is as below:
 7 – 12 years old: 10 mL (2 teaspoonfuls)
 2 – 7 years old: 5 mL (1 teaspoonful)
 9 months – 2 years old: 2.5 mL

Individuals with kidney and liver problems

- If your child has kidney problems the dose might be lowered.
- If your child has liver problems they may need more frequent blood tests to see how their liver is working.

Directions to use:

1. Shake the bottle to loosen the powder.
2. Take off the cap and fill the bottle with water up to the mark on the label.
3. Shake again until the powder dissolves completely.
4. Shake the bottle well before each use.

- When to take it

Take three times per day or as directed by your doctor or pharmacist.

Take with meal to reduce stomach discomfort.

- How long to take it

Take CAVUMOX SYRUP for the duration that the doctor recommends.

The treatment duration is usually up to 14 days. If your child's condition worsens or no improvement seen, please see the doctor again.

- If you forget to use it

Take the missed 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 you or anyone else may have use 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 CAVUMOX SYRUP may cause upset stomach, imbalance of electrolytes, formation of crystals in the urine, kidney problems or convulsions.

CAVUMOX SYRUP

Amoxicillin trihydrate / Clavulanic Acid (125 mg / 31.25 mg per 5 mL)

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking CAVUMOX SYRUP.
- Take CAVUMOX SYRUP only with a doctor's prescription.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give CAVUMOX SYRUP to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If your child develops diarrhoea while taking this medication, or even after finishing the course of the antibiotic, stop taking it and see the doctor immediately.

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 your child is taking CAVUMOX SYRUP. This is because CAVUMOX SYRUP can affect the results of these types of tests.

Side effects

Like all medicines, CAVUMOX SYRUP can cause side effects, although not everybody gets them.

CAVUMOX SYRUP may cause severe allergy and serious skin reactions.

Stop using CAVUMOX SYRUP and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

Stop taking CAVUMOX SYRUP and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Common side effects:

- Diarrhea
- Nausea
- Vomiting
- Fungal infection in mucous membranes and skin

Uncommon side effects:

- Dizziness
- Headache
- Indigestion
- Rises in liver enzymes
- Skin rash
- Itchiness
- Hives

Other side effects:

- Abnormal blood counts and bleeding disorder
- swelling of the skin, such as at face or throat (angioedema)
- inflammation of blood vessels which may be visible as red or purple raised spots on the skin, but can affect other parts of the body (hypersensitivity vasculitis)
- unusually active
- convulsions
- black hairy tongue
- inflammation of the liver (hepatitis)
- jaundice, which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- crystals in urine

If you get side effects, tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of CAVUMOX SYRUP

- Storage

Dry powder:

Store in a dry place below 25°C in the original packaging to protect from light and moisture.

After dilution:

Once diluted, the suspension must be stored in a refrigerator (2°C to 8°C) and used within 5 days. Do not freeze.

- Disposal

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.

Product description

- What it looks like

CAVUMOX SYRUP is a creamy white powder with characteristic odour supplied in an amber glass bottle. Once diluted, it became creamy white suspension.

- Ingredients

- Active ingredients

Each 5 ml suspension contains:
Amoxicillin (as amoxicillin trihydrate) 125 mg
Clavulanic acid (as potassium clavulanate) 31.25 mg.

- Inactive ingredients

D-mannitol, sodium citrate dihydrate, caramel, banana flavour, mint flavour, xanthan gum, aspartame.

- MAL number

MAL20014319AZ

CAVUMOX SYRUP

Amoxicillin trihydrate / Clavulanic Acid (125 mg / 31.25 mg per 5 mL)

Manufacturer:

Siam Bheasach Co., Ltd.,
123 Soi Chokechairuammitr,
Vibhavadi-Rangsit Road, Chomphon,
Chatuchak, Bangkok 10900 and 9
Soi Chokechairuammitr 3,
Vibhavadi-Rangsit Road, Dindang,
Dindang, Bangkok 10400, Thailand.

Product Registration Holder:

SPG Pharma (Malaysia) Sdn. Bhd.,
Suite 1701, Block A, Damansara
Intan e-Business Park,
No. 1, Jalan SS20/27, 47400 Petaling
Jaya, Selangor Darul Ehsan,
Malaysia.

Date of Revision

01/08/2024

Serial Number

NPRA(R4/1)310724/00095