

PHARMANIAGA CO-AMOXICLAV SUSPENSION 228MG

Amoxycillin trihydrate/Clavulanic acid (200mg/28.5mg)

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What Pharmaniaga Co-Amoxiclav Suspension is used for

Pharmaniaga Co-Amoxiclav Suspension is used in children to treat the following bacterial infections:

- respiratory tract infections
- skin and soft tissue infections
- urinary tract infections
- bone and joint infections

How Pharmaniaga Co-Amoxiclav Suspension works

Pharmaniaga Co-Amoxiclav Suspension contains two active ingredients which are amoxycillin trihydrate and clavulanic acid. Both are antibiotics that work by killing bacteria that cause infections.

Before you use Pharmaniaga Co-Amoxiclav Suspension

- When you must not use it

Do not take this medicine if:

- your child is allergic or ever had severe allergic to amoxicillin, clavulanic acid, other penicillin based antibiotics, or similar antibiotics called cephalosporins or any other ingredients of this medicine (listed in Product Description).
- your child has ever had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking antibiotic.

- Before you start to use it

Tell your doctor or pharmacist if:

- your child has liver or kidney problems
- your child has history of diarrhea during or after antibiotic therapy
- your child is not urinating regularly

If you are not sure if any of the above apply to your child, talk to your doctor or pharmacist before taking Pharmaniaga Co-Amoxiclav Suspension.

- Taking other medicines

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

You should tell your doctor if your child is taking the following medicine as it may interact with Pharmaniaga Co-Amoxiclav Suspension:

- probenecid and allopurinol (medicine for gout)
- oral contraceptives
- blood thinning medications (such as warfarin)
- mycophenolate mofetil (medicine used to prevent the rejection after organ transplant)
- methotrexate (medicine used to treat cancer or rheumatic diseases)

How to use Pharmaniaga Co-Amoxiclav Suspension

- How much to use

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.

For oral administration only.

The usual recommended daily dosage:

Children over 2 years

Mild to moderate infection:

- i. 2 to 6 years (13 – 21kg) – 5mL Pharmaniaga Co-Amoxiclav Suspension 2 times daily
- ii. 7 to 12 years (22 – 40 kg) – 10mL Pharmaniaga Co-Amoxiclav Suspension 2 times daily

Serious infection:

2 to 6 years (13-21kg) - 10mL Pharmaniaga Co-Amoxiclav Suspension 2 times daily

Children <2 months

Pharmaniaga Co-Amoxiclav Suspension is not recommended for children <2 months.

Infants with immature kidney function

Pharmaniaga Co-Amoxiclav Suspension is not recommended for infants with immature renal function.

Renal impairment

For children with a GFR of >30mL/min, no adjustment in dosage is required. For children with a GFR of <30mL/min, Pharmaniaga Co-Amoxiclav Suspension is not recommended.

Hepatic impairment

If your child has liver problems, you may have more frequent blood tests to check how your child liver is working. There is insufficient experience with Co-Amoxiclav Suspension to make dosage recommended child with liver problems.

- When to use it

Use as directed by your doctor or pharmacist.

Direction for mixing:

Shake the bottle to loosen the powder. Add freshly boiled and cooled water and shake well. Make up to the required volume as stated on the label.

Use reconstituted suspension within 7 days. Keep in refrigerator. Complete the prescribe course.

- How long to use it

Use Pharmaniaga Co-Amoxiclav Suspension for the duration that the doctor recommends.

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

Keep taking Pharmaniaga Co-Amoxiclav Suspension until the treatment is finished, even if your child feels better.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your child 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 anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. Your child may need urgent medical attention.

Taking too much Pharmaniaga Co-Amoxiclav Suspension may cause upset stomach, imbalance of electrolytes, formation of crystals in the urine, kidney problems or convulsions.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating your child that your child is using Pharmaniaga Co-Amoxiclav Suspension.

Take Pharmaniaga Co-Amoxiclav Suspension only with a doctor's prescription.

- Things you must not do

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

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

Do not give Pharmaniaga Co-Amoxiclav Suspension to anyone else, even if they have the same symptoms or condition as your child.

- Things to be careful of

If any skin reactions occur while taking this medication, stop taking it and see the doctor immediately.

If your child develop 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 Coomb's test (red blood cell status tests), let the doctor or nurse know that your child is taking Pharmaniaga Co-Amoxiclav Suspension, as this medicine can affect the test results.

Side effects

Like all medicines, Pharmaniaga Co-Amoxiclav Suspension can cause side effects, although not everybody gets them.

Stop taking Pharmaniaga Co-Amoxiclav Suspension and contact your doctor immediately if you experience any of the following:

- Serious allergic reaction 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.

Pharmaniaga Co-Amoxiclav Suspension may cause severe allergy and serious skin reactions. Stop using Pharmaniaga Co-Amoxiclav Suspension and seek medical assistance immediately if you experience any of the following symptoms:

- severe allergy: breathing difficulties, lightheadedness, skin swellings or rash
- severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

Very common and common side effects:

- diarrhea
- nausea
- vomiting

- fungal infection

Uncommon side effects:

- dizziness
- headache
- indigestion
- increase liver enzymes
- skin rash
- itchiness
- hives

Rare and very rare side effects:

- low white blood cells, red blood cells or platelets
- swelling of the skin (angioedema)
- inflammation of blood vessels which may be visible as red or purple raised spots on the skin (hypersensitivity vasculitis)
- unusually active
- convulsions
- black hairy tongue
- inflammation of the liver (hepatitis) & jaundice (yellowing of skin and whites of the eyes)
- inflammation of tubes in the kidney
- crystals in urine

Visit your doctor or pharmacist immediately if your child experiences any side effects after using this medicine.

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

Storage and Disposal of Pharmaniaga Co-Amoxiclav Suspension

- Storage

Keep out of the reach and sight of children.

Use reconstituted suspension within 7 days. Shake well before use.

Keep bottle tightly closed. Store below 30°C in a cool dry place. Protect from light and moisture. Keep in refrigerator after reconstituted (2°C to 8°C).

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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

The granules are white to yellowish and becomes a white to yellowish suspension with fruit flavoured after dissolved with water.

- Ingredients

- Active ingredient(s)

Each 5mL contains:

- amoxicillin trihydrate equivalent to amoxicillin 200mg
- potassium clavulanate equivalent to clavulanic acid 28.50mg

- Inactive ingredients

Succinic acid, xanthum gum, aspartame (powder), tutti frutti flavour, precipitated silicon dioxide and sucrose (castor).

- MAL number:

MAL20021372AZ

Manufacturer

INSPIRAPHARMA SDN BHD
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32610 Bandar Seri Iskandar,
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Product Registration Holder

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