

ENHANCIN SUSPENSION

Amoxicillin/clavulanic acid (312.5mg/5mL)

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What Enhancin is used for

Enhancin is used to treat the following bacterial infections in different parts of the body:

- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections, animal bites
- bone and joint infections

How Enhancin works

Enhancin Suspension is an antibiotic that contains amoxicillin and clavulanic acid, which works by killing bacteria that cause infections.

Before you use Enhancin

- When you must not use it

Do not give Enhancin to your child if they:

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

If you are not sure your child should take Enhancin Suspension or not, talk to their doctor or pharmacist before giving Enhancin.

- Before you start to use it

Tell your doctor if your child:

- have any viral infections (example, common cold)

- are being treated for liver or kidney problems
- are not urinating regularly

- Taking other medicines

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

Tell your doctor or pharmacist if your child is taking:

- probenecid, allopurinol (medication to treat gout/ joint disease)
- warfarin (to prevent blood clot)
- methotrexate (a medicine used to treat cancer or rheumatic diseases)
- mycophenolate mofetil (a medicine used to prevent the rejection of transplanted) organs.

How to use Enhancin

- How much to use

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

Shake the bottle to loosen the powder, add cooled boiled water upto the mark on bottle or as directed, invert and shake.

Enhancin Suspension is not suitable for adults and children weighing more than 40 kg.

Children weighing less than 40 kg

Your doctor will determine the dose based on the type of infection your child have and also their body weight (in kg):

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

Individuals 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 need more frequent blood tests to see how their liver is working.

- When to use it

Shake the bottle well before each use.

Give Enhancin Suspension three times daily or as directed by your doctor.

Give Enhancin Suspension with meal.

- How long to use it

Give Enhancin Suspension for the duration that the doctor recommends.

It is important that your child takes the full course of Enhancin. Don't stop unless your doctor advises you to – even if you're feeling better. If you don't complete the full course of treatment, the infection may come back.

Do not give your child Enhancin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

- If you forget to use it

If you forget to give your child a dose, give it as soon as you remember. If it is almost time for the next dose, wait until then to give the medicine and skip the missed dose. Do not give a double dose to make up for a forgotten dose. If you're not sure what to do, ask your doctor or pharmacist.

- 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. They may need urgent medical attention.

Taking too much of this medicine may cause upset stomach, presence of crystals in urine or convulsions (fits).

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Enhancin Suspension.

Take Enhancin Suspension only with a doctor's prescription

- Things you must not do

Do not stop using the medicine unless advised by doctor.

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

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

- Things to be careful of**Blood and urine tests**

If your child is having blood tests (such as Coombs or Aspergillus EIA tests) or urine tests (for glucose), let the doctor or nurse know that they are taking amoxicillin/ clavulanic acid. This is because amoxicillin/clavulanic acid can affect the results of these types of tests.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the suspensions make you feel dizzy, gives you an allergic reactions or convulsions, do not drive or use machines and contact your doctor immediately.

Enhancin contains aspartame and maltodextrin:

- Aspartame (E951) is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.
- Enhancin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before using this medicinal product.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, individuals can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, contact your doctor.

Stop giving Enhancin suspension and contact your doctor immediately if your child 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.
- skin reddening, blisters, rash, fever, sore throat or eye irritation.

The side effects that your child may get:

Common

- fungal infection
- nausea
- vomiting
- diarrhea

Uncommon

- dizziness
- headache
- indigestion
- abnormal liver function tests
- itchiness
- hives

Unknown frequency:

- low number of red blood cells
- blood takes longer to clot
- swelling of the skin, such as at face or throat (angioedema), causing difficulty in breathing
- 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

Rare

- reduction in white blood cells and platelet count
- tooth discoloration especially in children

Tell your doctor or pharmacist if any of the side effects listed becomes 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 visiting the website npra.gov.my

[Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Enhancin**- Storage**

Store below 30°C, protected from moisture

Once dissolved in water, the suspension should be stored in a refrigerator at a temperature between 2 to 8°C and used within 7 days.

Keep out of the reach and sight of children

- 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**

White to off - white powder forming a white to pale yellow suspension after dissolved with water.

- Ingredients**- Active ingredient(s)**

Each 5ml solution contains Amoxicillin 250 mg and Clavulanic Acid 62.5 mg

- Inactive ingredients

Butylated Hydroxytoluene, Xanthan Gum, Monosodium Citrate, Sodium Citrate, Passion Fruit Flavour, Aspartame, Sorbitol, Sodium Benzoate

- MAL number(s):

MAL20001809AZ

Manufacturer

Manufactured in India by Sun Pharmaceutical Ind. Ltd. Industrial Area - 3, Dewas - 455 001 India.

Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

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