

ENHANCIN TABLET

Amoxicillin/ clavulanic acid (500mg/125mg)

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What Enhancin Tablet is used for

Enhancin Tablet are to treat the following infections:

- respiratory tract infections
- urinary tract infection
- skin and soft tissue infections (e.g. boils, wound)
- dental infections
- bone and joint infections.
- other infections

How Enhancin Tablet works

Enhancin Tablet is an antibiotic that contains amoxicillin and clavulanate, which works by killing bacteria that cause infections.

Before you start to use Enhancin Tablet

- When you must not use it

Do not take Enhancin Tablet if you:

- are allergic to amoxicillin, clavulanate, other penicillin-based antibiotics, or similar antibiotics called cephalosporins or any 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 whether you should start taking Enhancin Tablet, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor if you:

- have viral infections (eg: common cold)

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Enhancin Tablet.

Pregnancy and Lactation

Amoxicillin/ clavulanate potassium is secreted into the breast milk.

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Avoid the use of the medicine in the first three months of pregnancy unless advised by doctor.

- Taking other medicines

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

- Probenecid and allopurinol (used for gout)
- medicines to help stop blood clots (such as warfarin)
- Oral contraceptives that contain oestrogen. You should take additional precautions to prevent pregnancy while you are receiving Enhancin Tablet
- Methotrexate (a medicine used to treat cancer or rheumatic diseases).

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

How to use Enhancin Tablet

- How much to use

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

Your doctor will tell you how much Enhancin Tablet you need to take. This will depend on the type of infection you have.

Tablets should be swallowed whole without chewing.

- Adults and children weighing 40 kg and over

The usual dose is 1 tablet two times a day to be taken at an interval of 12 hrs.

For more severe infections and infections of the respiratory tract, the dose should be one tablet 625 mg every 8 hours.

Tablet are not suitable for children weighing less than 40 kg.

- Individuals with kidney and liver problems

- If you have severe kidney or liver problems, your doctor might change the dose.

- When to use it

Take Enhancin Tablet at the start of a meal.

- How long to use it

Use Enhancin Tablet for the duration that your doctor recommends.

Do not take Enhancin Tablet for more than 2 weeks. Tell your doctor if you still feel unwell.

It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. Your infection may continue to grow or worsen if you do not complete the antibiotic course.

- 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 think you or anyone else may have used 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 many tablets may cause gastrointestinal symptoms, presence of crystals in urine or convulsions.

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 Tablet.

Tell your doctor immediately if you become pregnant while you are taking this medicine.

Take Enhancin Tablets 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 Enhancin Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Blood and urine tests

If you are having blood tests (Coombs or Aspergillus EIA tests) or urine tests (for glucose), tell your doctor or nurse that you are taking Enhancin Tablet. This is because Enhancin Tablet can affect the results of these types of tests.

Side effects

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.

Like all medicines, Enhancin Tablet can cause side effects, although not everybody gets them.

Enhancin Tablet may cause severe allergy and serious skin reactions.

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

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with rash on the face and the extended rash, high temperature and enlarged lymph nodes.
- Skin reddening, blisters, rash, fever, sore throat or eye irritation

Tell your doctor if you notice any of the following and they worry you:

Very common

- Diarrhoea

Common

- Fungal infection
- Nausea
- Vomiting

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 for example at the 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) and 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 staining especially in children

Other side effects

- Agitation
- Anxiety
- Behavioral changes
- Confusion
- Difficulty sleeping
- Blood in urine
- Vaginal infection

Ask your doctor or pharmacist to answer any questions you may have.

Visit your doctor or pharmacist immediately if you experience 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 npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Enhancin Tablet

Do not use this medicine after the expiry date printed on the pack has expired or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

- Storage

Keep medicine out of the reach of children.

Store below 30°C, protected from moisture

- 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 film coated oval shaped tablets debossed with "RX713" on one side and plain on the other

- Ingredients

Active ingredients:

Amoxicillin trihydrate equivalent to
amoxicillin...500 mg

Potassium clavulanate equivalent to
clavulanic acid....125 mg

Inactive ingredients:

Microcrystalline cellulose, sodium starch
glycolate, colloidal silicon dioxide,
povidone (K30), eudragit E 100,
isopropyl alcohol, magnesium stearate,
opadry 03B58965 white, polyethylene
glycol-400, methylene chloride

- MAL number(s):

MAL20000018AZ

Manufacturer

Sun Pharmaceutical Ind. Ltd.
Industrial Area - 3
Dewas- 455001, India

Product Registration Holder

Ranbaxy (Malaysia) SDN. Bhd.
(A Sun Pharma Company)
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Malaysia

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