

**Enalapril Maleateis Cas No. : 76095-16-4**

You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day.

If you are taking this drug in the liquid suspension form, shake the bottle well before each use. Measure the dose out carefully.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

**Taj Pharmaceuticals Ltd.****Enalapril Maleateis****CAS No. : 76095-16-4**

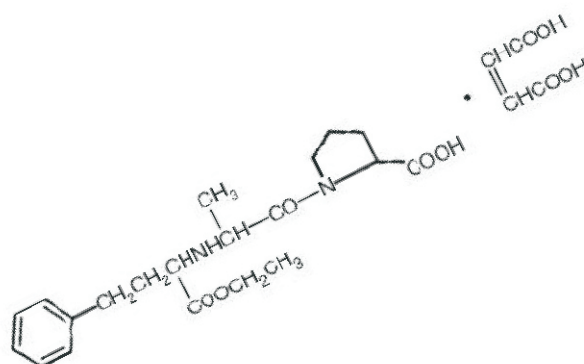
Enalapril Maleateis the maleate salt of enalapril, the ethyl ester of a long-acting angiotensin converting enzyme inhibitor, enalaprilat. Enalapril maleate is chemically described as (S)-1-[N-[1-(ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline, (Z)-2-butenedioate salt.

Its empirical formula is  $C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$ . structural formula is:

Enalapril maleate is a white to off-white, crystalline powder with a molecular weight of 492.53. It is sparingly soluble in water, soluble in ethanol, and freely soluble in methanol.

Enalapril is a pro-drug; following oral administration, it is bioactivated by hydrolysis of the ethyl ester to enalaprilat, which is the active angiotensin converting enzyme inhibitor.

Enalapril maleate is supplied as 2.5 mg, 5 mg, 10 mg, and 20 mg tablets for oral administration. In addition to the active ingredient enalapril maleate, each tablet contains the following inactive ingredients: lactose, magnesium stearate, sodium bicarbonate, and starch. The 10 mg and 20 mg tablets also contain iron oxides.

**WARNING**

This drug can cause serious (possibly fatal) harm to an unborn baby if used during pregnancy. Therefore, it is important to prevent pregnancy while taking this medication. Consult your doctor for more details and to discuss the use of reliable forms of birth control while taking this medication. If you are planning pregnancy, become pregnant, or think you may be pregnant, contact your doctor immediately. **USES:** This drug belongs to a group of medications called ACE inhibitors. It is used to treat high blood pressure (hypertension) in adults and children. It works by relaxing blood vessels, causing them to widen. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. This medication is also used with other drugs (e.g., "water pills"/diuretics, digoxin) to treat congestive heart failure.

**HOW TO USE:** You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day.

If you are taking this drug in the liquid suspension form, shake the bottle well before each use. Measure the dose out carefully.

Do not take potassium supplements or salt substitutes containing potassium without talking to your doctor or pharmacist first. This medicine can raise your potassium levels, which rarely can cause serious side effects such as muscle weakness or a very slow heartbeat. Tell your doctor immediately if either of these effects occur.

The dosage is based on your medical condition and response to therapy. The usual maximum dose for adults is 40 milligrams per day.

It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick. For the treatment of high blood pressure, it may take several weeks before the full benefit of this drug occurs or several weeks to months when used for congestive heart failure.



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**SIDE EFFECTS**

You may experience headache, dizziness, lightheadedness, weakness, nausea, dry cough, or blurred vision as your body adjusts to the medication. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: fainting, decreased sexual ability. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: change in the amount of urine, signs of infection (e.g., fever, chills, persistent sore throat).

This drug may rarely cause serious (possibly fatal) liver problems. If you notice any of the following highly unlikely but very serious side effects, seek immediate medical attention: yellowing eyes or skin, dark urine, stomach/abdominal pain, persistent fatigue, persistent nausea.

A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling (especially of the face, lips, tongue, or throat), severe dizziness, trouble breathing.

**PRECAUTIONS**

Before taking enalapril, tell your doctor or pharmacist if you are allergic to it; or to other ACE inhibitors (e.g., benazepril, captopril); or if you have any other allergies (including an allergic reaction after exposure to certain membranes used for blood filtering).

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: history of an allergic reaction which included swelling of the face/lips/tongue/throat (angioedema).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, high blood levels of potassium, heart problems, severe dehydration (and loss of electrolytes such as sodium), low blood flow to the brain (cerebrovascular insufficiency), blood vessel disease (e.g., collagen vascular diseases such as lupus, scleroderma).

If you have diabetes, enalapril may rarely cause low blood sugar levels (hypoglycemia) when you first start treatment with this medication. Carefully monitor your blood sugar level during the first month of enalapril therapy. Treat symptoms of low blood sugar quickly and report any hypoglycemia event to your doctor immediately.

This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

To minimize dizziness and light-headedness due to lowering of your blood pressure, get up slowly when rising from a seated or lying position. Serious loss of body fluids can also lower your blood pressure and worsen dizziness. Drink adequate fluids to prevent from becoming dehydrated. If you are on restricted fluid intake, consult your doctor for further instructions. Be careful not to become too overheated during exercise which can lead to excessive sweating. Consult your doctor if you experience severe vomiting or diarrhea.



## MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

## STORAGE

Store tablets at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Refrigerate the liquid suspension between 36-46 degrees F (2-8 degrees C). Discard any unused suspension after 30 days. Keep all medicines away from children and pets.

## DOSAGE

Take this medication by mouth, usually once or twice a day; or as directed by your doctor. You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day. If you are taking this drug in the liquid suspension form, shake the bottle well before each use. Measure the dose out carefully. Do not take potassium supplements or salt substitutes containing potassium without talking to your doctor or pharmacist first. This medicine can raise your potassium levels, which rarely can cause serious side effects such as muscle weakness or very slow heartbeats. Tell your doctor immediately if these effects occur. The dosage is based on your medical condition and response to therapy. For the treatment of high blood pressure, it may take several weeks before the full benefit of this drug occurs or several weeks to months when used for congestive heart failure. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick.

Enalapril maleate can be taken with or without food.

Do not use salt substitutes containing potassium without first consulting your doctor.

Take Enalapril maleate exactly as prescribed by your doctor.

If you miss a dose...

Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Never take two doses at the same time.

**Note /Government Notification:** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:

91 022 30601000.

This leaflet was prepared by  
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