

ACETEC TABLET

Enalapril Maleate 5 mg/20 mg

Consumer Medication Information Leaflet (RiMUP)

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What Acetec is used for

Acetec is used in the treatment of high blood pressure, whether alone or in combination with other anti-hypertensive drugs especially diuretics.

It is also used in the treatment of congestive heart failure. Should be used as an adjunctive therapy with digitalis and/or diuretics.

How Acetec works

Enalapril is an angiotensin converting enzyme (ACE) inhibitor. Enalapril is a prodrug and will be transformed to enalaprilat (active form of Enalapril) by liver. Acetec can reduce blood pressure in a normal and hypertensive person by reducing the resistance of blood vessels but has no effect on the heart rate.

Before you use Acetec

- When you must not use it

Do not take Acetec if:

- You are allergic (hypersensitive) to Enalapril maleate or any of the other ingredients of Acetec.
- You have ever had an allergic reaction to other ACE inhibitor which is the same group of medicine as Acetec.
- You are pregnant, breast-feeding or thinking of becoming pregnant.

- Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You have a heart problem.
- You have a blood problem such as neutropenia, agranulocytosis, anemia, thrombocytopenia.
- You have a kidney problem (including kidney transplantation).

- You are on a salt – restricted diet, are taking potassium supplements, potassium – sparing agents, or potassium – containing substitutes.
- You are over 70 years of age.
- You have low blood pressure.

- Taking other medicines

When administered concurrently, the following drugs may interact with Enalapril: antihypertensive drug, potassium-sparing diuretics or potassium preparation, potassium-losing diuretics, lithium, digoxin, allopurinol, rifampin, phenothiazine and indomethacin.

How to use Acetec

- How much to use

Treatment for High Blood Pressure: The initial dose is 10-20 mg depending on the degree of hypertension and is given once daily. The usual maintenance dose is one 20 mg tablet taken once daily

High blood pressure due to narrowing of the arteries that carry blood to the kidneys (Renovascular Hypertension):

Therapy should be initiated with a lower starting dose (e.g. 5 mg or less).

Concomitant Diuretic Therapy in high blood pressure: The initial dose of Acetec should be low (5 mg or less) to determine the initial effect on the blood pressure.

Dosage in Kidney Insufficiency: Generally, the intervals between the administrations of Enalapril should be prolonged and/or the dosage reduced.

Heart Failure and/or Symptomatic Left Ventricular Dysfunction: The initial dose of Acetec in patients with symptomatic heart failure or symptomatic left ventricular dysfunction is 2.5 mg and it should be administered under close medical supervision to determine the initial effect on the blood pressure. The dose should be increased gradually to the usual maintenance dose of 20 mg, given in a single dose or 2 divided doses, as tolerated by the patient. This dose titration may be performed over a 2 to 4 week period, or more rapidly if indicated by the presence of residual signs and symptoms of heart failure.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Always take Acetec exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

- If you forget to use it

If you forget to take, skip the missed dose and take the next dose as usual. Do not take a double dose to make up forgotten dose.

- If you use too much (overdose)

If you take more Acetec than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effect may happen: feeling of light – headed or dizziness. This is due to a sudden or excessive drop in blood pressure.

While you are using it

- Things you must do

If you develop any of the following symptoms you should let your doctor know immediately;

- Jaundice
- A dry cough which is persistent for a long time.
- The diuretic therapy should be discontinued for 2 - 3 days prior to initiation of therapy with Acetec.

- Things you must not do

Do not stop taking your medicine, unless your doctor has advised you to do so.

- Things to be careful of

When used in pregnancy during the second and third trimesters ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, this drug should be discontinued as soon as possible. Cautions should be exercised if Acetec is given to a nursing mother.

Side effects

- Low blood pressure
- Renal function disturbance such as the excretion of glucose and protein in urine
- Skin: excess perspiration or sweating,

hair loss, allergic reactions (swelling of face, eyes, lips and tongue, rash, itching)

- Gastrointestinal: vomiting, constipation abdominal pain, indigestion, jaundice, loss of appetite, inflammation of mouth, inflammation of pancreas and liver failure

- Laboratory test findings: Low blood sodium, low white blood cell, low platelet count, bone marrow suppression, high potassium level in the blood

- Respiratory: Unwanted substance within the lungs (pulmonary infiltrates), bronchospasm/asthma, shortness of breath, runny nose, sore throat, dry and lasting cough

- Nervous system/psychiatric: Confusion, nervousness, insomnia, depression, finger numbness

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Acetec

Storage

Store at temperature not exceeding 30°C. Protect from moisture.

Keep medicines out of reach 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

ACETEC 5 mg: Heart-shape, white tablet impressed “BIOLAB” on one surface and bisected on the obverse

ACETEC 20 mg: Heart-shape, light orange tablet impressed “BIOLAB” on one surface and bisected on the obverse

Ingredients

- Active ingredient:

Enalapril Maleate

- Inactive ingredients:

ACETEC 5 mg: Corn Starch, Lactose Monohydrate, Purified Water, Povidone (PVP K-30), Microcrystalline Cellulose, Sodium Bicarbonate and Magnesium Stearate.

ACETEC 20 mg: Corn Starch, Lactose Monohydrate, Purified Water, Povidone (PVP K-30), Microcrystalline Cellulose, Sodium Bicarbonate, Magnesium Stearate and Sunset Yellow Lake.

- MAL number(s):

ACETEC 5 mg: MAL 19990017A

ACETEC 20 mg: MAL 19990018A

Manufacturer

BIOLAB CO., LTD.

625Moo 4, Bangpoo Industrial Estate Soi 7A, Sukhumvit Road, Prakasa, Muang, Samutprakarn 10280, Thailand.

Product Registration Holder

MEDISPEC (M) SDN.BHD

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Date of revision

6/8/2014