

ENCARDIL TABLET

Enalapril maleate (5mg and 10mg)

What in this Leaflet

1. What Encardil Tablet is used for
2. How Encardil Tablet works
3. Before you use Encardil tablet
4. How to take Encardil Tablet
5. While you are using Encardil Tablet
6. Side Effects
7. Storage and Disposal of Encardil Tablet
8. Product Descriptions
9. Manufacturer and Product Registration Holder
10. Date of revision

What Encardil Tablet is used for

- Treatment of hypertension (high blood pressure).
- Treatment of congestive heart failure.
- Prevention of symptomatic heart failure.
- Prevention of coronary ischemic events in patients with left ventricular dysfunction.

How Encardil Tablet works

Enalapril belongs to the group of medications known as angiotensin-converting enzyme (ACE) inhibitors. It relaxes the blood vessels and widens them for easier blood flow. Lowering of blood pressure reduces the pressure of arteries and lessens the damage to heart and kidneys.

Before you use Encardil tablet

When you must not take it

- If you are hypersensitive to any component of this product, or any other ACE inhibitor.
- If you have a history of angioneurotic oedema (swelling of areas of skin) relating to previous ACE inhibitor therapy or with hereditary angioedema or idiopathic angioedema (no known cause for symptoms of swelling).

Before you start to take it

- Enalapril Maleate is strictly prohibited for pregnant mothers. The drug should be immediately stopped as soon as the pregnancy is detected.
- Do not take potassium supplements or salt supplements with potassium in them when taking Enalapril Maleate.

Taking other medicines

- Alcohol or Diuretics (water pills) or other hypotension-producing medications. Concurrent usage with ACE inhibitors may produce additive hypotensive effects.
- Indomethacin, Cyclosporine or Diuretics, potassium-sparing or Low-salt milk or Potassium-containing medications or Potassium supplements or substances containing high concentrations of potassium or salt substitutes. - concurrent usage not recommended.
- Bone marrow depressants - concurrent usage not recommended.
- Estrogens, Lithium, Sympathomimetics - concurrent usage not recommended.

How to take Encardil Tablet

How much to take

Since absorption of Encardil Tablet is not affected by food, the tablets may be administered before, during or after meals.

• **Essential Hypertension:**

The initial dose is 5 to 20 mg, depending on the degree of hypertension, once daily.

An initial dose of 5 mg of enalapril maleate daily may be given, if you have normal kidney function and not receiving a diuretic (water pills).

In mild hypertension, the recommended initial dose is 10 mg daily. For other degrees of hypertension the initial dose is 20 mg daily. The usual maintenance dose is 10 – 20 mg taken once daily. The maximum recommended dose is 40mg daily.

- **Renovascular hypertension** (due to narrowing of the arteries that carry blood to the kidneys):
Lower starting dose (eg 5mg or less).

When to take it

The tablets may be administered before, during or after meals depending on the degree of hypertension.

This is only recommendation, for actual dosages please always refer to your doctor or pharmacists.

How long to take it

Follow doctor advice.

If you forget to take it

Take the missed dose as soon as possible as you remember it. However if it is almost time for the next dose, skip the missed dose and continue with your regular schedule. Do not take a double dose to make up for a missed one.

If you take too much (overdose)

Hypotension and stupor (a state of near-unconsciousness).

Get medical help as soon as possible if above symptoms is observed.

While you are using Encardil Tablet

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all doctors, dentist, and pharmacist treating you that you are taking Encardil.
- Tell your doctor immediately if you become pregnant while taking this medication.

ENCARDIL TABLET

Enalapril maleate (5mg and 10mg)

Things you must not do

Do not stop taking without consulting doctor first.

Do not give your medicine to others experiencing the same symptoms as you.

Things to be careful of

- ***Symptomatic Hypotension-***
This is more likely to occur in those patients with more severe degrees of heart failure.
- ***Kidney Function Impairment-***
In some patients, hypotension following the initiation of therapy with ACE inhibitors may lead to some further impairment in kidney function.
- ***Hypersensitivity / Angioneurotic Edema-***
Angioneurotic edema (Recurring episodes of noninflammatory swelling of the skin, mucous membranes) of the face, extremities, lips, tongue, glottis and / or larynx has been reported rarely in patients treated with ACE inhibitors.
- ***Haemodialysis***
Anaphylactoid (hypersensitive state that may develop after introduction of a foreign protein or other antigen into the body tissues) reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN69) and treated concomitantly with an ACE inhibitor.
- ***Surgery / Anesthesia-***
In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril blocks angiotensin II formation secondary to compensatory renin release.
- ***Cross-sensitivity and / or related problems-***
Patients sensitive to one ACE inhibitor may also be sensitive to another.

- ***Pregnancy-***
The use of Encardil during pregnancy is not recommended. ACE inhibitors should be discontinued as soon as possible when pregnancy is detected.
- ***Use in Lactation-***
Caution should be exercised if Encardil is given to a nursing mother.
- ***Paediatrics***
Appropriate studies on the relationship of age to the effects of ACE inhibitors have not been done in the paediatric population.
- ***Geriatrics***
Since plasma renin activity appears to decline with increasing age, elderly individuals may be less sensitive to the hypotensive effects of ACE inhibitors.

Side Effects

Dizziness and headache, nausea, diarrhoea, muscle cramps, rash and cough.

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Encardil Tablet

Storage

Store below 25°C. Protect from light & moisture and KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Disposal

Medicines should not be disposed of via waste water or household waste.

These measures will help you to protect the environment.

Ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks Like

5 mg: A white, round, flat, beveled edged tablet, with break line on one side.

10 mg: A white, triangle shaped, biconvex tablet embossed with 'SM' on one side.

Ingredients:

Active Ingredient used is Enalapril Maleate 5 mg or 10 mg.

Inactive ingredient used for 5 and 10mg are cross carmellose sodium, lactose, Aerosil, Malic Acid, Microcrystalline Cellulose, Zinc Stearate and for 10 mg Corn starch is also used.

MAL Numbers.:

5mg MAL 20040569A

10mg MAL20040570A

Manufacturer and Product Registration Holder

SM PHARMACEUTICALS
SDN.BHD(218628-M)
Lot 88,Sungai Petani Industrial Estate
08000,Sungai Petani
Kedah Darul Aman,Malaysia

Date Revision : 27.10.2014

Serial Number:

BPFK(R4/1)241014/00036