

INVORIL TABLET

Enalapril Maleate (5mg, 10mg and 20mg)

What is in this leaflet

1. What INVORIL TABLET is used for
2. How INVORIL TABLET works
3. Before you use INVORIL TABLET
4. How to use INVORIL TABLET
5. While you are using INVORIL TABLET
6. Side effects
7. Storage and Disposal of INVORIL TABLET
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What INVORIL TABLET is used for

INVORIL TABLET contain the active ingredient enalapril maleate. It is used:

- to treat high blood pressure (hypertension)
- to treat heart failure (weakening of heart function). It can lower the need to go to hospital and can help some patients live longer
- to prevent the signs of heart failure. The signs include: shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet.
- to reduce the incidence of heart attack and reduce hospitalisation for unstable angina pectoris (a feeling of tightness, pressure or heaviness in the chest)

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

Ask your doctor if you want more information.

This medicine is available only with a doctor's prescription.

How INVORIL TABLET works
INVORIL TABLET (enalapril) belongs to a group of medicines

called angiotensin converting enzyme (ACE) inhibitors.

One of the ways INVORIL TABLET helps to lower blood pressure and treat heart failure is that it widens your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body. This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get breathless as easily.

Before you use INVORIL TABLET

- When you must not use it
Do not take INVORIL TABLET:

If you are allergic to enalapril, or any of the ingredients of the tablets (see Product Description at the end of this leaflet).

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to INVORIL TABLET.

If you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (symptoms of allergic reaction) when the reason why was not known or it was inherited.

During 2nd & 3rd trimester of pregnancy (last 6 months of pregnancy; it is also better to avoid

enalapril in early pregnancy)

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.

If you are not sure whether you should start taking INVORIL TABLETS, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.

Tell your doctor if you have any medical conditions, especially the following:

- kidney disease (including kidney transplantation), or are undergoing dialysis
- liver problems
- problems with your blood vessels (collagen vascular disease)
- have recently suffered from excessive vomiting or diarrhoea
- diabetes
- heart problems
- have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up
- you are of black origin as enalapril may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction) having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take enalapril while you are having this treatment, it may cause a severe allergic reaction
- have high levels of cholesterol and you are having a treatment called 'LDL apheresis'
- are following a very low salt diet

Pregnancy and lactation

Talk to your doctor before taking INVORIL TABLETS if you think you are (or might become) pregnant or are currently breast-feeding.

INVORIL TABLETS are not recommended in early pregnancy, and must not be taken if you are more than

3 months pregnant, as it may cause serious harm to your baby if used at that stage.

If you have not told your doctor about any of the above, tell them

before you start taking INVORIL TABLETS.

Your medicine also contains an inactive ingredient called lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.

- Taking other medicines

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.

Some medicines and INVORIL TABLETS may interact with each other including:

Potassium supplements, salt substitutes that have potassium in them or potassium sparing diuretics such as spironolactone, eplerenone, triamterene or amiloride Lithium (a medicine used to treat a certain kind of depression) Medicines for depression called 'tricyclic antidepressants' (for example: amitriptyline, imipramine, desipramine, nortriptyline) Medicines for mental problems called 'antipsychotics' (for example: clozapine, fluoxetine, olanzapine, chlorpromazine, haloperidol, pimozide & risperidone) Other medicines to lower blood pressure, such as beta-blockers (for example: atenolol, metoprolol, carvedilol) or water tablets (Diuretics)

Non-steroidal anti-inflammatory medicines (NSAIDs), including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) [for example: celecoxib, ibuprofen, naproxen, diclofenac, indomethacin]

Gold therapy such as sodium aurothiomalate, which can lead to flushing of your face, feeling sick (nausea), being sick (vomiting) and low blood pressure

Medicines for diabetes (including oral antidiabetic medicines and insulin). Enalapril may cause your

blood sugar levels to drop even further when taken with these medicines. This is more likely to occur during the first weeks of taking enalapril

Alcohol

Sympathomimetic agents used for treating cough, cold and asthma Aspirin (acetylsalicylic acid) Medicines used to dissolve blood clots (thrombolytics)

Allopurinol (for gout)

Cytostatic or immune-suppressive agents (cyclosporin)

Procainamide (for heart beat problems)

Nitrate medicines (for heart problems)

If you have not told your doctor about any of these, tell them before you take INVORIL TABLETS.

Consult your doctor before you start taking another medicinal product.

Your doctor will consider if INVORIL TABLETS should be used together with any of these medicines, or may wish to adjust the dose of the other medicines.

How to use INVORIL TABLET

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

If you do not understand the instructions on this leaflet, ask your doctor or pharmacist for help.

- How much to use

Hypertension:

The usual starting dose is 5 mg taken

once a day. Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure. Most patients take between 10 to 40 mg each day.

If you are an elderly patient (over 65 years of age) or if you have kidney problems, your doctor will start your treatment INVORIL TABLET on a lower dose and

adjust your dose according to your response and blood pressure.

If you are taking water tablets (diuretics), your doctor will adjust the dose of INVORIL TABLET or water tablets according to your response and blood pressure.

Heart failure/Asymptomatic Left Ventricular Dysfunction:

The usual starting dose is 2.5 mg taken

once daily. Depending on your response, this dose may need to be increased up to 20 mg each day (as single dose or two divided doses).

DO NOT INCREASE OR ADJUST YOUR DOSE YOURSELF.

- How to take it

INVORIL TABLETS can be taken with or without food. Swallow INVORIL TABLETS with a glass of water.

- When to use it

Take INVORIL TABLETS exactly as your doctor tells you to take it.

Take INVORIL TABLETS at the same time every day. Keeping a regular time for taking INVORIL TABLETS will help to remind you to take it.

- How long to use it

INVORIL TABLETS helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore, INVORIL TABLETS must be taken every day. Continue taking INVORIL TABLETS for as long as your doctor prescribes.

- If you forget to use it

It is important to take your medicine every day as regular treatment works better.

Do not miss a dose of INVORIL TABLETS. If you miss a dose of INVORIL TABLETS, take the missed dose as soon as you remember. If it is almost time for your next dose of INVORIL TABLETS, do not take the missed dose. Take the next dose of

INVORIL TABLETS at your regular time.

If you are not sure what to do, ask your doctor or pharmacist. Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- *If you use too much (overdose)*

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of INVORIL TABLETS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take this leaflet or some tablets with you so your doctor will know what you have taken.

While you are using INVORIL TABLET

- *Things you must do*

If you feel any light-headedness or dizziness after you take your first dose of INVORIL TABLET or if your dose is increased, tell your doctor immediately. This is especially important if you are taking INVORIL TABLET for heart failure.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking INVORIL TABLET.

Tell your doctor or pharmacist that you are taking INVORIL TABLET if you are about to be started on any new medicines.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking

INVORIL TABLET. Your blood pressure may drop suddenly.

Tell your doctor if you are receiving LDL apheresis with dextran sulphate. INVORIL TABLET need to be discontinued prior to each apheresis treatment.

Make sure you drink enough water during exercise and hot weather when you are taking INVORIL TABLET, especially if you sweat a lot.

If you do not drink enough water while taking INVORIL TABLET, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excessive vomiting and/or diarrhoea while taking INVORIL TABLET, tell your doctor. This can also mean that you are losing too much water and salt, and may drop your blood pressure too much.

Go to your doctor regularly for a check-up. Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g., potassium) in your blood at regular intervals.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

- *Things you must not do*

Do not stop taking INVORIL TABLETS or alter the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use INVORIL TABLETS to treat any other complaints unless your doctor says to.

- *Things to be careful of* INVORIL TABLET may cause dizziness or light-headedness in some people, especially after the first dose or if the dose is increased. Make sure

you know how you react to INVORIL TABLET before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

Side Effects

Like all medicines, INVORIL TABLET can have side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them

Very serious side effects

If any of the following happens, stop taking Invoril Tablets and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- severe skin reaction with painful red areas, large blisters, bleeding in the lips, eyes, mouth, nose, genitals, and peeling of layers of skin.
- changes in heart rhythm, fast heartbeat, chest pain, stroke and heart attack
- difficulty in breathing, wheeziness due to tightness in the chest or asthma

These are very serious side effects. If you have them you may need urgent medical attention or hospitalisation.

Serious side effects

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- serious lung infection. Symptoms include fever, chills, shortness of breath, cough, phlegm and occasionally blood blockage of lung artery and build-up of pus in the lungs
- light-headedness or dizziness because blood pressure is too low

- decreased blood cell production and abnormal blood cell counts.
- Symptoms include tiredness, headaches, being short of breath
- when exercising, dizziness and looking pale, bleeding or bruising more easily than normal, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- raynaud's phenomenon where your hands and feet may become very
- cold and white due to low blood flow
- fainting
- cough
- inflammation of your pancreas. Symptoms include severe upper stomach pain, often with nausea and vomiting
- abdominal pain, vomiting, diarrhoea, or reduced appetite due to swelling of the wall of bowel.
- hepatitis or jaundice (yellow eyes or skin), liver failure
- kidney or urination problems, kidney failure

The above list includes serious side effects that may require medical attention.

Other side effects

Tell your doctor if you notice any of the following:

- nausea, vomiting, diarrhoea, taste alteration, stomach pain, dark stools, dry mouth, stomach ulcer, indigestion, constipation, loss of appetite, irritated stomach
- blockage in the bowel. Symptoms include persistent constipation with swollen stomach and vomiting
- confusion, nervousness, depression
- sleepiness, trouble in sleep, numbness or weakness of the arms and legs, spinning sensation
- feeling dizzy, unusual weakness, blurred vision
- runny nose, sore throat or hoarseness
- excessive sweating, rash, itching, hives, hair loss

- tiredness, headache
- low blood pressure
- impotence
- muscle cramps, ringing in the ears, flushing, generally feeling unwell, high temperature
- a condition which may include some or all of the following: high temperature, inflamed blood vessels, painful inflamed muscles and joints, blood problems detected by a blood test, rash, very sensitive to sunlight or other effect on skin.

Laboratory Abnormalities

- increase in potassium levels, blood creatinine, blood urea, serum bilirubin, liver enzymes
- decrease in sodium levels
- decreases in haematocrit, abnormal blood cell counts
- low blood sugar
- presence of protein in urine

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of INVORIL TABLET

- Storage

Store below 30°C, protected from moisture.

- Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

- What it looks like
INVORIL TABLETS 5 MG

White, barrel shaped uncoated tablets embossed with '5' on one side and scored on other side.

INVORIL TABLETS 10 MG

Peach, barrel shaped uncoated tablets embossed with '10' on one side and scored on other side.

INVORIL TABLETS 20 MG

Light yellow, barrel shaped uncoated tablets embossed with '20' on one side and scored on other side

- Ingredients

- Active ingredient:

Enalapril Maleate

- Inactive ingredients:

Colloidal Anhydrous Silica, Croscarmellose Sodium, Zinc Stearate, Purified Talc, Microcrystalline Cellulose, Lactose, Maleic acid, Sunset Yellow Lake, Ferric Oxide (Yellow)

- MAL Number:

Invoril Tablets 5MG:
MAL20000067AZ

Invoril Tablets 10MG:
MAL20000066AZ

Invoril Tablets 20MG:
MAL20000065AZ

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah, Malaysia.

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