

# **Arrow - Enalapril**

**Enalapril 5 mg, 10 mg and 20 mg tablets**

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## **What is in this leaflet**

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Please read this leaflet carefully before you start using ARROW – ENALAPRIL.

This leaflet answers some common questions about ARROW - ENALAPRIL. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using ARROW - ENALAPRIL against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

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## **What ARROW - ENALAPRIL is used for**

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ARROW - ENALAPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. It is used to treat high high blood pressure (hypertension) and heart failure.

### ***Hypertension***

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. ARROW - ENALAPRIL helps to lower your blood pressure.

### ***Heart Failure***

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

### ***How ARROW - ENALAPRIL works***

ARROW - ENALAPRIL works by widening 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 short of breath easily.

Your doctor may have prescribed ARROW - ENALAPRIL for another reason. Ask your doctor if you have any questions about why ARROW - ENALAPRIL has been prescribed for you.

ARROW – ENALAPRIL is not addictive.

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

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## **Before you take ARROW - ENALAPRIL**

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### ***When you must not use it***

**Do not use ARROW - ENALAPRIL if:**

- you have taken any other 'ACE inhibitor' medicines for high blood pressure or heart failure before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe.  
If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to ARROW - ENALAPRIL.
- you have an allergy to ARROW - ENALAPRIL or any of the ingredients listed at the end of this leaflet.  
Symptoms of an allergic reaction to ARROW - ENALAPRIL may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.
- you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.

**Do not take ARROW - ENALAPRIL if you are pregnant or breastfeeding.**

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

**Do not take ARROW - ENALAPRIL if the expiry date (Exp.) printed on the pack has passed.**

It may not work well if you do.

**Do not take ARROW - ENALAPRIL if the packaging is torn or shows signs of tampering.**

### ***Before you start to use it***

Tell your doctor if:

1. you intend to become pregnant or intend to breast-feed.  
ARROW - ENALAPRIL should not be used during pregnancy or while breast-feeding.
2. you have any medical conditions, especially the following:
  - heart problems
  - if you are undergoing dialysis or are being treated with diuretics (water tablets)
  - diabetes or any kidney problems, as these may lead to increased levels of potassium in the blood which can be serious
3. you are following a very low salt diet, are taking potassium supplements, potassium-sparing agents or potassium-containing salt substitutes
4. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes
5. you have recently suffered from excessive vomiting or diarrhoea.

In these cases, your doctor may need to adjust the dosage of ARROW - ENALAPRIL or monitor your blood level of potassium. If you have diabetes and are taking oral anti-diabetic

medicines or insulin, you should closely monitor for low blood glucose levels, especially during the first month of treatment with ARROW - ENALAPRIL.

If you have not told your doctor about any of the above, tell them before you take any ARROW - ENALAPRIL.

ARROW - ENALAPRIL has been studied in children. For more information talk to your doctor.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and ARROW - ENALAPRIL may interfere with each other. These include:

- other medicines used to treat high blood pressure
- diuretic tablets - also called fluid or water tablets
- medicines for diabetes (including oral anti-diabetic medicines and insulin)
- lithium, a medicine used to treat mood swings and some types of depression
- potassium tablets
- potassium-containing salt substitutes
- non-steroidal anti-inflammatory medicines (including gold therapy), used to relieve pain, swelling and other symptoms of inflammation and arthritis

These medicines may be affected by ARROW - ENALAPRIL, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to avoid while taking ARROW - ENALAPRIL.

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## **How to take ARROW - ENALAPRIL**

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### ***How much to take***

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. Take ARROW - ENALAPRIL only when prescribed by your doctor.

### ***For high blood pressure***

For most patients, the usual starting dose is 5 mg taken once a day. Some patients may need a lower starting dose. The usual maintenance dose is 20mg taken once a day. The dose may need to be increased to a maximum of 40mg depending on your blood pressure.

### ***For heart failure***

The usual starting dose is 2.5 mg taken once a day. Depending on your response, this dose may need to be increased up to 20 mg each day. This dose may be taken once a day or divided into two doses per day.

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

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

### ***How to take it***

Take your ARROW - ENALAPRIL at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

Swallow ARROW - ENALAPRIL with a glass of water.

It does not matter if you take ARROW - ENALAPRIL before or after food.

### ***How long to take it***

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

### ***If you forget to take it***

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to 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 tablets, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARROW - ENALAPRIL. Do this even if there are no signs of discomfort or poisoning.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

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## **While you are taking ARROW - ENALAPRIL**

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### ***Things you must do***

Have your blood pressure checked when your doctor says, to make sure ARROW - ENALAPRIL is working.

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

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

You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This may be because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you become pregnant while taking ARROW - ENALAPRIL, tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking ARROW - ENALAPRIL.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ARROW - ENALAPRIL. Your blood pressure may drop suddenly.

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

If you do not drink enough water while taking ARROW - ENALAPRIL, 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 ARROW - ENALAPRIL, 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 occasionally do a blood test to check your potassium level in the blood and to see how your kidneys are working.

### ***Things you must not do***

Do not give ARROW - ENALAPRIL to anyone else, even if they have the same condition as you.

### ***Things to be careful of***

Be careful driving or operating machinery until you know how ARROW - ENALAPRIL affects you.

ARROW - ENALAPRIL 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 ARROW - ENALAPRIL 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.

### ***Things that would be helpful for your blood pressure or heart failure***

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking - your doctor may advise you to stop smoking or at least cut down.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

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## **Side effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - ENALAPRIL.

ARROW - ENALAPRIL helps most people with high blood pressure and heart failure, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

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

- light-headedness or dizziness because blood pressure is too low
- headache
- fatigue
- dry cough
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps
- taste disturbances
- difficulty sleeping or strange dreams
- sexual problems
- ringing or buzzing in the ears
- feelings of deep sadness or unworthiness
- pain in joints
- hair loss or thinning

These are usually mild adverse effects of ARROW - ENALAPRIL, but may be serious.

**Tell your doctor immediately if you notice any of the following:**

- blurred vision
- changes in the way your heart beats, for example, if you notice it beating faster
- fainting
- yellowing of the skin and eyes, also called jaundice
- symptoms of sunburn which may occur more quickly than normal
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less urine than is normal for you

These may be serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

**If any of the following happen, stop taking ARROW - ENALAPRIL and tell your doctor immediately or go to accident and emergency at your nearest hospital:**

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- chest pain, angina
- wheeziness due to tightness in the chest
- collapse, numbness or weakness of arms or legs

These are serious adverse effects. You may need urgent medical attention or hospitalisation.

All of these adverse effects are rare.

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

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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## After taking ARROW - ENALAPRIL

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### **Storage**

**Keep ARROW - ENALAPRIL where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep ARROW - ENALAPRIL in a cool, dry place where the temperature stays below 25°C.**

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

**Do not store ARROW - ENALAPRIL or other medicines in the bathroom or near a sink.**

**Do not leave the tablets in the car or on window sills.**

Heat, light and dampness can destroy some medicines.

### **Disposal**

If your doctor tells you to stop taking ARROW - ENALAPRIL, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## Product Description

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### **What ARROW - ENALAPRIL looks like**

ARROW - ENALAPRIL is available in 3 different strengths of tablets:

- ARROW - ENALAPRIL 5 – White to off-white barrel-shaped tablet with “EL” scoreline “5” on one side and “>” on reverse side.
- ARROW - ENALAPRIL 10 – Salmon coloured, barrel-shaped tablet with “EL 10” on one side and “>” on reverse side.
- ARROW - ENALAPRIL 20 – Peach coloured, barrel-shaped tablet with “EL 20” on one side and “>” on reverse side.

### **Ingredients**

The active ingredient in ARROW - ENALAPRIL tablets is enalapril maleate:

- each ARROW - ENALAPRIL 5 tablet contains 5 mg of enalapril maleate
- each ARROW - ENALAPRIL 10 tablet contains 10 mg of enalapril maleate
- each ARROW - ENALAPRIL 20 tablet contains 20 mg of enalapril maleate.

The tablets also contain:

- lactose
- magnesium stearate
- maize starch
- pregelatinised maize starch
- sodium bicarbonate
- red iron oxide (10mg and 20 mg tablets)
- yellow iron oxide (10mg tablets)

*The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.*

***Supplier***

ARROW - ENALAPRIL is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited  
Mount Eden Central Business Park  
33a Normanby Road, Mt Eden  
Auckland, New Zealand.

***Date of preparation***

5 May 2010