

ENAHEXAL® TABLET

Enalapril maleate

Enahexal® 5mg Tablet Enahexal® 20mg Tablet

The products *Enahexal® 5mg Tablet* and *Enahexal® 20mg Tablet* are referred to as **Enahexal** throughout this leaflet.

WHAT IS IN THIS LEAFLET?

This leaflet answers some common questions about **Enahexal**. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet; you may need to read it again.

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1. WHAT ENAHEXAL IS USED FOR

Enahexal is used to treat high blood pressure (hypertension) and heart failure.

Enahexal is often used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body. **Enahexal** is also commonly used with digitalis, a medication for heart failure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

2. HOW ENAHEXAL WORKS

Enahexal belongs to a group of medicines known as angiotensin

converting enzyme (ACE) inhibitors. These medicines work by widening your blood vessels to make it easier for the heart to pump blood through them to all parts of your body. This helps to reduce high blood pressure and increase the supply of oxygen to your heart, so that when you place extra demand on your heart, such as during exercise, your heart may cope better and you may not get short of breath easily. **Enahexal** will also help your heart to work better if you have a damaged heart muscle.

3. BEFORE YOU TAKE ENAHEXAL

Do not take this medicine if you:

- Have an allergy to the active ingredient enalapril maleate or to any of the other ingredients in this preparation.
- 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.

Do not take this medicine if you are pregnant, plan to become pregnant or are 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 give this medicine to children. The safety and effectiveness in children have not been established. If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as enalapril maleate
- any other substances, including foods, preservatives or dyes.

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

- kidney problems, or if you are undergoing dialysis treatment
- heart problems
- diabetes
- low blood pressure
- any allergic reaction to insects bite (eg. Bees or wasp) and are undergoing desensitization treatment for such allergy conditions.
- if you have recently suffered from excessive vomiting or diarrhea.
- if you are following a very low salt diet.

If you have not told your doctor about any of the above, tell him/her before you start taking **Enahexal**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription. Some medicines and **Enahexal** may interfere with each other. These include:

- other medicines used to treat high blood pressure
- diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation
- potassium supplements or potassium containing salt substitutes
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride)
- lithium, a medicine used to treat mood swings and some types of depression
- insulin or oral antidiabetic medicines.

Anesthetics agent and narcotics may also cause exaggerated hypotensive response

Your blood glucose level should be closely monitored especially during the first month of treatment with **Enahexal**. The medicines stated above may affect how well **Enahexal** works. Your dosage may be adjusted by your

doctor or you may need to take different medicines while you are taking **Enahexal**.

4. HOW TO TAKE **ENAHEXAL**

Take your medication exactly as directed by your doctor.

How much to take

The dose given by your doctor may differ from this leaflet.

For hypertension, the usual dose is 5mg – 40mg (max) per day, depending on tolerance and conditions. For patients receiving diuretic at the same time, the initial dose of **Enahexal** could be adjusted lower to 2.5mg. For heart failure, normally 2.5mg – 20mg (max) per day, depending on patient response. For patients receiving diuretic at the same time, the dose should be reduced if possible before initiating treatment with **Enahexal**. For patients with moderately impaired renal function and patients of more than 65 years of age, the dose is 2.5mg-20mg (max) per day. For patients with severe renal functions disorders (creatinine clearance less than 30ml /min) and dialysis the initial dose is 2.5mg and the maximum dose is 10mg per day.

When to take

Enahexal can be taken before or after food. It is taken once a day, usually in the morning and to be swallowed with water.

Try to take **Enahexal** at the same time each day to for best effects.

Haemodialysis patients are advised to take the dose after dialysis.

How long to take it

Enahexal is meant for long term medication. Take **Enahexal** as long as you are told by your doctor.

If you forget to take it

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Bring the carton or any remaining tablets you have left.

Symptoms might not be noticeable until hours later.

5. WHILE YOU ARE USING **ENAHEXAL**

Observe and report incidents of light-headedness, especially during the first few days of therapy, it could be symptomatic hypotension. Observe any possible side effects / serum potassium level especially when diuretic is co-administered

Things you must do

- Always follow your doctor's instructions carefully.
- If you feel any light-headedness or dizziness after you take your first dose of **Enahexal** or after your dose is increased, tell your doctor immediately. This is especially important if you are taking **Enahexal** for heart failure.
- If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.
- If this problem gets worse or continues, talk to your doctor.
- If you are pregnant, or planning to become pregnant while taking **Enahexal**, tell your doctor immediately.
- If you are about to start taking any new medicine, remind your doctor and pharmacist that you are taking **Enahexal**
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking **Enahexal**
- If you are planning or going to start desensitization treatment for allergic reaction towards insects bite, remind your doctor that you are taking **Enahexal**.
- If you are about to have any blood tests, tell your doctor that you are taking **Enahexal**. It may interfere with the results of some tests.
- Make sure you drink enough water during exercise and in hot weather when you are taking **Enahexal**, especially if you sweat a lot. If you do not drink enough water while taking **Enahexal**, you may faint or feel lightheaded 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 **Enahexal**, tell your doctor. This can also mean that you are losing too much water and salt, and may cause your blood pressure to drop too much.
- Visit 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 stop taking **Enahexal** without your doctor's permission.
- Do not give this medication to anyone else, even if they have the same condition as you

Things to be careful of

- **Enahexal** may cause dizziness or lightheadedness in some people, especially after the first dose or if the dose is increased.
- Make sure you know how you react to **Enahexal** before you drive a car, operate machinery, or do anything else that could be dangerous. Drinking alcoholic beverages may worsen the symptoms.

6. POSSIBLE SIDE EFFECTS

Like all medicines, **Enahexal** can cause side effects, although not everybody gets them.

Stop taking **Enahexal** and talk to a doctor straight away, if you notice any of the following:

- swelling of your face, lips, tongue or throat which may cause difficulty in breathing or swallowing.
- swelling of your hands, feet or ankles
- development of raised red skin rash (hives).

Other common side effects after you start to take **Enahexal** are feeling dizzy, weak or sick, tiredness (fatigue), diarrhea and nausea. This is caused by the lowering of your blood pressure. When you feel dizzy or faint, it will help to lie down. Your condition should improve as you continue to take the medicine. If you are worried, please talk to your doctor. Apart from this you may experience some of these side effects:

- **Nervous System Effects:** confusion, depression, nervousness, sleeplessness, sleepiness, feeling your skin prickling or being numb, vertigo (spinning sensation), disturbance of balance.
- **Gastro-intestinal Effects:** dry mouth, loss of appetite, vomiting, constipation, dyspepsia, abdominal pain, dark stool, inflammations (tongue/ mouth/ pancreas/ liver/ intestine)
- **Cardiovascular Effects:** Low blood pressure, cardiac arrest, heart attack, chest pain, palpitation, blood clot in the lung, retention of fluid in the lung, rhythm disturbances
- **Renal Effects :** Pain at one side of body, small urine volume, kidney failure
- **Hypersensitivity and Skin Reactions:** swelling of the face, extremities, lips, tongue and/or larynx, joint pain, muscle pain, fever, rash etc. abnormal increase in the number of white blood cells, eosinophils, photosensitivity, excessive sweating, rashes, itchiness, redness of the skin, skin peeling, skin blistering, Stevens-Johnson syndrome, development of herpes zoster, hair loss, and other possible allergic reactions.
- **Haematological Effects:** changes in blood values such as a lower number of white and red blood cells, lower of haemoglobin level, lower number of blood platelets, bone marrow depression, autoimmune diseases
- **Respiratory Effects:** Cough, nasal congestion, difficulty in breathing, wheezing, lung/airway inflammation/ spasm, asthma, sore throat, hoarseness, runny nose, swelling, upper respiratory infection.
- **Other Adverse Effects:** Muscle cramps, impotence, decreased libido, flushing, hearing loss, ringing sensation in the ear, blurred vision, taste alteration, liver failure, conjunctivitis (pink eye) dry eyes, tearing eyes, development of breast in male, muscle pain, genital itching, burning urination

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your

doctor or pharmacist or return them to your doctor /pharmacist for disposal.

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

7. STORAGE AND DISPOSAL OF ENAHEXAL

Storage

Keep medicines in original packaging. Store in a cool (below 30°C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car. Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

Enahexal® 5mg Tablet: Oval, convex, white snap tab tablets, one side scored with marking of 'EN 5'.

Enahexal® 20mg Tablet: Oval, convex, orange snap tab tablets, one side scored with marking of 'EN 20'.

Enahexal contains:

Enalapril maleate as the active ingredient.

Other ingredients:

Lactose monohydrate, maize starch, sodium hydrogen carbonate, talc, magnesium stearate, hydroxypropylcellulose (**Enahexal 5mg Tablet** only), iron oxide red and iron oxide yellow (**Enahexal 20mg Tablet** only)

Packing:

Blisters pack of 30, 50 and 100 tablets.

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufactured by:

1. Salutas Pharma GmbH
Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

(for Enahexal® 5mg Tablet: MAL20014482ACZ, and Enahexal® 20mg Tablet: MAL20014484ACZ)

2. Ilsan Ilac ve Hammaddeleri San. Ve Tic.A.S.,
Gebze Plastikciler Organize, Sanayi Bolgesi, 41400 Ataturk Bulvari 9.
Cadde, No: 1, Turkey
(for Enahexal® 20mg Tablet: MAL07122778ASZ)

For

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

Marketing Authorization Holder:

Idaman Pharma Sdn Bhd
No.15&17, Jalan Wangsa Delima 1A,
Seksyen 5, Pusat Bandar Wangsa Maju, 53300 Kuala Lumpur

Authorized Importer and Distributor:

IMEKS Pharma Sdn. Bhd.
No.5&9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur. Malaysia

Registration No:

Enahexal® 5mg Tablet:
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Enahexal® 20mg Tablet:
MAL20014484ACZ and
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