

## **Package leaflet: Information for the patient**

### **Milorex 5 mg/50 mg tablets**

amiloride hydrochloride dihydrate /hydrochlorothiazide

**Read all of this leaflet carefully before you start taking the medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Milorex is and what it is used for
2. What you need to know before you take Milorex
3. How to take Milorex
4. Possible side effects
5. How to store Milorex
6. Contents of the pack and other information

#### **1. What Milorex is and what it is used for**

Milorex contains amiloride and hydrochlorothiazide. They belong to the group of medicines known as water tablets (diuretics). They work by increasing the amount of urine that passes from your body. This lowers your blood pressure or removes excess water from your body.

Milorex is used for:

- heart failure.
- high blood pressure.
- fluid retention caused by a liver disease called 'cirrhosis'.

#### **2. What you need to know before you take Milorex**

##### **Do not take Milorex**

- if you are allergic to amiloride hydrochloride dihydrate and hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- if you have diabetes (a high blood sugar level).

- if you have been told by your doctor you have high levels of urea, creatinine, potassium or calcium in your blood.
- if you are allergic to a type of antibiotic called sulfonamides, such as sulfamethoxazole.
- if you are allergic to acetazolamide which is a diuretic used to remove fluid from the body and to treat high pressure in the eye (glaucoma), heart problems and sometimes fits of epilepsy.
- if you are allergic to any other ‘thiazide’ water tablet (diuretic).
- if you are taking potassium sparing water tablets (diuretics) such as eplerenone, spironolactone or triamterene.
- if you are taking a potassium supplement or medicine containing potassium or you eat potassium-rich foods.
- if you suffer from kidney or liver disease.
- if you have Addison’s disease.

Do not take Milorex if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Milorex.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Milorex if:

- you have been told by your doctor you have high levels of uric acid, cholesterol or triglycerides (a type of cholesterol) in your blood.
- you are taking digitalis such as digoxin – used for heart failure and abnormal heart beat.
- you are being given fluids by a tube inserted into one of your veins.
- you have recently suffered from severe vomiting or diarrhoea.
- you have Systemic Lupus Erythematosus.
- you are elderly.
- you have gout.
- you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Milorex.
- you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Milorex. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Milorex, seek medical attention immediately.

If you are not sure talk to your doctor or pharmacist before taking Milorex.

### **Children and adolescents**

Do not give this medicine to children under 18 years of age as limited data is available.

### **Other medicines and Milorex**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Milorex can affect the way some other medicines work. Also some other medicines can affect the way Milorex works.

It is important to tell your doctor or pharmacist if you take:

- angiotensin converting enzyme inhibitors (ACE inhibitors) such as enalapril used to treat high blood pressure or heart problems.
- angiotensin II receptor antagonists such as losartan - used to treat high blood pressure or diabetics with kidney damage.
- other medicines for high blood pressure.
- medicines for diabetes such as insulin or chlorpropamide.
- lithium - used for depression.
- non steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen - used to reduce high temperature (fever), pain or for arthritis.
- barbiturates - used to help you sleep or to reduce anxiety.
- painkillers such as codeine, dihydrocodeine, dextropropoxyphene, diamorphine, morphine, pentazocine and pethidine.
- cholestyramine and colestipol - used to treat high cholesterol (hyperlipidaemia).
- steroids - used to treat lots of different conditions such as rheumatism, arthritis, allergic conditions, skin problems, asthma or a type of blood disorder.
- ACTH to test whether your adrenal glands are working properly.
- medicines injected for allergic reactions such as adrenaline (also known as epinephrine).
- tacrolimus - used after a liver or kidney transplant to prevent rejection.
- ciclosporin - used for rheumatoid arthritis or to prevent rejection after a transplant.
- 'non-depolarising' muscle relaxants such as tubocurarine.
- Trilostane - used to treat breast cancer or overactive adrenal glands (such as in Conn's syndrome, Cushing's syndrome).

In addition, if you are going to have an operation, make sure the doctor treating you knows you are taking Milorex.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Milorex.

### **Tests while you are taking Milorex**

When you are on this medication it may affect some tests on blood or urine samples. Please remind your doctor you are taking Milorex if he or she wants you to have any tests. If you

have diabetes or your doctor suspects you have diabetes, you may need to have some tests before receiving treatment with Milorex.

### **Milorex with food, drink and alcohol**

Your doctor may have asked you to change your diet slightly and not to eat certain foods which contain a lot of potassium. These foods include milk, bananas, raisins and prunes. Your doctor will tell you what food you should not eat. If you are unsure about what food you should avoid, ask your doctor before taking Milorex.

Your doctor may have told you that you should keep alcohol intake to a minimum while you are taking Milorex. Alcohol may increase the effects of Milorex so that you feel dizzy or light-headed when you stand up quickly.

### **Pregnancy and breast-feeding**

#### Pregnancy

You must tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby. Usually, your doctor will advise you to take another medicine instead of Milorex, as Milorex is not recommended during pregnancy. This is because Milorex crosses the placenta and its use after the third month of pregnancy can cause potentially harmful fetal and neonatal effects.

#### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Milorex is not recommended for mothers who are breast-feeding.

### **Driving and using machines**

This medicine may make you feel tired or dizzy. Do not drive or operate machinery until you have discussed this with your doctor or you know if you are affected.

### **Excipients warnings**

#### **Milorex contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Milorex contains sunset yellow FCF E110.**

May cause allergic reactions.

#### **Milorex contains sodium.**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Milorex**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should take this medicine by mouth. The amount you take each day will depend on your illness. The number of tablets to be taken will be on the label of your medicine.

The recommended doses are:

**High blood pressure**

- the usual starting dose is half a tablet each day.
- your doctor may change your dose to one tablet given each day.
- your doctor may spread out the dose or give it as a single dose.

**Heart failure**

- the usual starting dose is half a tablet each day.
- your doctor may change your dose.
- you should not take more than two tablets in a day.

**Fluid retention due to cirrhosis**

- the usual starting dose is one tablet each day.
- your doctor may change your dose.
- you should not take more than two tablets in a day.

The tablet can be divided into equal doses.

**If you take more Milorex than you should**

If you take too much Milorex by mistake, contact your doctor or seek medical help immediately.

**If you forget to take Milorex**

- if you forget to take your dose, skip the missed dose.
- take the next dose as normal.
- do not take a double dose to make up for a forgotten dose.

**If you stop taking Milorex**

Do not stop taking Milorex without speaking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

**Stop taking Milorex and see a doctor straight away, if you notice any of the following serious side effects that may rarely occur. You may need urgent medical treatment:**

- allergic reactions – the signs may include inflamed blood vessels, difficulties breathing or swallowing, collapse, redness, blisters, peeling skin, muscle pains, chills, a general feeling of being unwell, ulcers in your mouth, eyes or genitals.

### **Other side effects include:**

#### Allergic reactions

- purplish or reddish-brown spots, skin irritation, increased sensitivity to sunlight and nettle like rash (urticaria).

#### Heart and circulation

- irregular heart beat of your heart that can lead to fainting and dizziness, palpitations.
- feeling light headed when you stand quickly.
- fast heart beat, chest pains (angina).

#### Blood

- anaemia – signs include unusual tiredness or loss of colour in the lining of the eyes and skin around the eyes.
- other blood disorders which can result in high temperature (fever), a sore throat, being unable to stop bleeding from a cut.
- changes in the levels of various chemicals in the blood which are usually detected by blood or urine tests.

#### Stomach and gut

- feeling sick (nausea) or being sick (vomiting), indigestion, diarrhoea, constipation, stomach ache and stomach cramps, wind, bloated feeling, hiccups.
- bleeding from your gut – signs may include blood in your faeces or a darker colour of faeces.
- liver problems such as jaundice – signs may include yellowing of the skin and/or whites of the eyes.
- an inflamed pancreas – signs may include feeling sick (nausea) and being sick (vomiting) with pain in the stomach area and back.
- swelling of the glands that make saliva.
- your mouth may become dry.
- a bad taste in your mouth.
- lack or loss of appetite.
- feeling thirsty.

#### Chest

- difficulty breathing.
- blocked nose.
- cough.

Very rare: acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

#### Nervous system

- feeling dizzy, feeling like you are spinning (vertigo), pins and needles.

- feeling sleepy, or sometimes feeling that you can not sleep.
- stupor, a type of brain disorder called encephalopathy.
- feeling nervous, confused, depressed or restless.
- feeling shaky (tremors).
- headache, blackouts.

#### Skin and hair

- flushing, sweating.
- rash, itching.
- hair loss.

#### Eyes or ears

- an increase in the pressure in the eye which is usually picked up in eye examinations.
- changes in vision.
- ringing in the ears.
- frequency 'not known': Skin and lip cancer (Non-melanoma skin cancer).
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

#### Joints and muscles

- joint pain, pain in the fingers and toes, gout.
- neck, shoulder and back pain.
- leg ache, muscle cramps.

#### Urinary

- difficulty or pain urinating, an increase in the amount of urine passed.
- contractions of the bladder which can lead to an increase in how often you need to pass urine.
- kidney disorders which may lead to a reduced amount of urine passed.
- passing urine at night, incontinence.

#### Sexual

- lower sex drive.
- impotence.

#### General/Other

- a general feeling of being unwell, feeling tired, weakness, dehydration.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

### **Malta**

ADR Reporting Website:

## **5. How to store Milorex**

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton or label after 'EXP'. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

## **6. Contents of the pack and other information**

### **What Milorex contains**

- The active substances are amiloride hydrochloride dihydrate and hydrochlorothiazide. Each tablet contains amiloride hydrochloride dihydrate equivalent to 5 mg anhydrous amiloride hydrochloride and 50 mg hydrochlorothiazide.

- The other ingredients are lactose, povidone, maize starch, sodium starch glycolate, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, talc, sunset yellow lake FCF E110.

See section 2 'Excipients warnings'.

### **What Milorex looks like and contents of the pack**

Peach-coloured, diamond-shaped tablets, embossed with Remedica's logo on one side and scored and embossed with 5/50 and MLX on the other side.

### **Pack sizes:**

PVC/Aluminium blisters. Pack size of 30 tablets.

PP containers with PE closure. Pack size of 1000 tablets.

Not all pack sizes may be marketed.

### **Marketing Licence Holder and Manufacturer**

Remedica Ltd,  
Aharnon Str., Limassol Industrial Estate,  
3056 Limassol, Cyprus

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