

Moduretic®

5/50 mg tablets

Amiloride hydrochloride and Hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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1. WHAT MODURETIC® IS AND WHAT IT IS USED FOR

Moduretic® is a combination of two medicines called 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.

Moduretic® is used for:

- Fluid retention due to heart failure
- High blood pressure
- Fluid retention caused by a liver disease called cirrhosis

2. BEFORE YOU TAKE MODURETIC®

Moduretic® tablets are not for use in children.

Do not take Moduretic® if:

- you have ever had an allergic reaction to this medicine or to any of its ingredients (listed in section 6).
- you have diabetes (a high blood sugar level).
- you have been told by your doctor you have high levels of urea, creatinine, potassium or calcium in your blood.
- you are allergic to any other 'thiazide' water tablet (diuretic).
- you are taking potassium sparing water tablets (diuretics) such as eplerenone, spironolactone or triamterene.

- you are taking a potassium supplement or medicine containing potassium or you eat potassium-rich foods.
- you suffer from kidney or liver disease.
- you have Addison's disease
- 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 or epilepsy.
- you are allergic to a type of antibiotic called sulphonamides, such as sulphamethoxazole.

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

Take special care with Moduretic®

- Check with your doctor or pharmacist before taking your medicine 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 diarrhea.
 - you have Systemic Lupus Erythematosus (autoimmune disease whereby a person's immunity attacks various organs such as skin, joints, kidney, brain...).
 - you are elderly.
 - you have gout (a chronic condition involving acute attacks of joint inflammation).

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

Taking Moduretic® with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Moduretic® can affect the way some other medicines work. Also some other medicines can affect the way Moduretic® 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 bipolar disorder
- non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen - used to relieve pain
- 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 (hyperlipidemia)
- 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
- muscle relaxants such as tubocurarine
- trilostane - used to treat breast cancer or overactive adrenal glands (such as in Conn's syndrome, Cushing's syndrome).

Tests

- Check with your doctor or pharmacist before taking your medicine:
- If you are undergoing some tests on blood or urine samples.
 - If you have diabetes or your doctor suspects you have diabetes, you may need to have some tests before receiving treatment with Moduretic®.

Taking Moduretic® with food and alcohol

- Drinking alcohol with Moduretic® may make you feel dizzy or light-headed when you stand up. If you are concerned about how much you can drink while you are taking Moduretic®, discuss this with your doctor.
- Your doctor may have asked you to change your diet slightly and not to eat certain foods which contain a lot of potassium (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 Moduretic® tablets.

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant. You should not take Moduretic® if you are pregnant, are

planning to become pregnant or are breast-feeding. If you become pregnant while on Moduretic®, tell your doctor immediately.

Driving and using machines

You may feel dizzy, while taking Moduretic®. This is more likely to happen when you start taking Moduretic® or start taking a higher dose. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE MODURETIC®

Always take Moduretic® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth at the same time of day each day, usually in the morning.
- Swallow the tablets with liquid.
- Do not crush or chew the tablets.

How much to take

- High blood pressure:
- Usual starting dose is half a tablet (5/50 mg) each day.
 - Your doctor will adjust your dose according to the need.

Fluid retention due to heart failure:

- Usual starting dose is half a tablet (5/50 mg) each day.
- Your doctor will adjust your dose according to the need.

Fluid retention due to cirrhosis:

- Usual starting dose is one tablet (5/50 mg) each day.
- Your doctor will adjust your dose according to the need.
- You should not take more than two tablets each day.

If you take more Moduretic® than you should

Tell a doctor or go to the nearest hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Moduretic®

If you miss a dose, take your normal dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Moduretic® can cause side effects, although not everybody gets them.

Stop taking Moduretic® and see a doctor straight away, if you notice any of the following serious side effects - 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:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

- Allergic reactions:
 - purplish or reddish-brown spots, skin irritation, increased sensitivity to sunlight and a nettle like rash (urticaria)
- Heart and circulation:
 - irregular heartbeat that can lead to fainting and dizziness, palpitations
 - feeling light-headed when you stand quickly
 - fast heartbeat, chest pains (angina)
- Blood:
 - anemia - signs include unusual tiredness or loss of color 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, diarrhea, constipation, stomach ache and stomach cramps, wind, bloated feeling, hiccups
 - bleeding from your gut - signs may include blood in your feces or a darker color of feces
 - 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
- Nervous system:
 - feeling dizzy, feeling like you are spinning (vertigo), pins and needles
 - feeling sleepy, or sometimes feeling that you cannot 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
- 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 being passed
 - passing urine at night, incontinence
- Sexual:
 - lower sex drive
 - impotence
- General/Other:
 - a general feeling of being unwell, feeling tired, weakness, dehydration

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.

5. HOW TO STORE MODURETIC®

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original package. Do not use Moduretic® tablets after the expiry date

shown on the carton and the blisters. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Moduretic® contains

Moduretic® 5/50 mg contains 5 mg amiloride hydrochloride and 50 mg hydrochlorothiazide. Excipients: calcium hydrogen phosphate, guar gum, lactose, magnesium stearate, corn starch and aluminium lake FD&C yellow #6.

What Moduretic® looks like and contents of the pack

Moduretic® tablets are peach biconvex diamond-shaped tablets, one side plain, the other engraved "ALG MDRT". The pack contains 30 tablets.

For more information about this medicinal product, please contact:

Algorithm SAL
Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries

Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgx.net
Website: www.algorithm-lb.com

Also contact the relevant competent authority.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

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