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PACKAGE LEAFLET: INFORMATION FOR THE USER

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MODURET® 25 mg/2.5 mg tablets

(Hydrochlorothiazide & Amloride Hydrochloride)

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Moduret 25 is and what it is used for

2. Before you take Moduret 25

3. How to take Moduret 25

4. Possible side effects

5. How to store Moduret 25

6. Further information

1. What Moduret 25 is and what it is used for

Moduret 25 contains amloride 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. Moduret 25 is used for high blood pressure.

2. Before you take Moduret 25

Moduret 25 tablets are not for use in children

Do not take Moduret 25 tablets 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 a type of antibiotic called sulphonamides, such as sulphamethoxazole
- 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 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 are taking lithium, a medicine used for depression
- you suffer from kidney or liver disease
- you have Addison's disease
- you have difficulty passing urine

Do not take Moduret 25 if any of the above applies to you.

If you are not sure talk to your doctor or pharmacist before taking Moduret 25.

Take special care with Moduret 25

Check with your doctor or pharmacist before taking Moduret 25 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.

If you are not sure talk to your doctor or pharmacist before taking Moduret 25.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Moduret 25 can affect the way some other medicines work. Also some other medicines can affect the way Moduret 25 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 diabetes 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
- cyclosporin, - used for rheumatoid arthritis or to prevent rejection after a transplant
- 'non-depolarising' muscle relaxants such as tubocurarine.

If you are going to have an operation, make sure the doctor treating you knows you are taking Moduret 25.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Moduret 25.

Tests while you are taking Moduret 25

When you are on this medication it may affect some tests on blood or urine samples. Please remind your doctor you are taking Moduret 25 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 Moduret 25

Taking Moduret 25 with food and drink

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 Moduret 25 tablets.

Your doctor may have told you that you should keep alcohol intake to a minimum while you are taking Moduret 25. Alcohol may increase the effects of Moduret 25 so that you feel dizzy or light-headed when you stand up quickly.

Pregnancy and breast-feeding

Do not take Moduret 25 if you are pregnant, are planning to become pregnant or 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.

Important information about some of the ingredients of Moduret 25

Moduret 25 contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

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Profile Revision Date:050708

Dimensions (mm):148 x 260

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3. How to take Moduret 25

Taking this medicine

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. If you are unsure about the dose you should take, you must talk to your doctor or pharmacist. The usual doses of Moduret 25 are:

High blood pressure

- The usual starting dose is one tablet each day.
- Your doctor may spread out the doses or give it all together as a single dose.

If you take more Moduret 25 than you should

If you take too much Moduret 25 by mistake, contact your doctor immediately or seek medical help immediately.

If you forget to take Moduret 25

- 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 Moduret 25

Do not stop taking Moduret 25 without speaking to your doctor.

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

4. Possible side effects

Like all medicines, Moduret 25 can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Moduret 25 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.

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

- changes in the levels of various chemicals in the blood which are usually detected by blood or urine tests.
- Reduction in the number of white blood cells, red blood cells or platelets.

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
- 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
- jaundice (yellowing of the skin or whites of the eyes)
- inflammation of the pancreas

Chest

- difficulty breathing
- blocked nose
- cough
- inflammation of the lungs
- accumulation of fluid in the lungs

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, hair, eyes and ears

- flushing, sweating
- rash, itching
- hair loss
- hearing problems
- visual disturbance

Joints and muscles

- joint pain, gout
- neck, shoulder and back pain
- leg ache, muscle cramps
- pain in extremities

Urinary

- difficulty or pain urinating
- kidney disorders
- passing urine at night, incontinence

Sexual

- impotence
- decreased libido.

General/Other

- a general feeling of being unwell, feeling tired, weakness, dehydration
- sensitivity to light
- fever

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Moduret 25

Keep your medicine out of the sight and reach of children. Do not use the medicine past the expiry date which is stated on the carton after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture. Keep container in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Moduret 25 contains

Active ingredients

The active ingredients in Moduret 25 tablets are amiloride hydrochloride and hydrochlorothiazide. Each Moduret 25 tablet contains 2.5 mg amiloride hydrochloride and 25 mg hydrochlorothiazide.

Other ingredients:

The other ingredients are calcium hydrogen phosphate dihydrate (E341), guar galactomannan, lactose monohydrate, magnesium stearate (E572), maize starch and pregelatinised maize starch.

What Moduret 25 looks like and contents of the pack

Moduret 25 tablets are off-white, diamond-shaped tablets. Moduret 25 is available in calendar packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Merck Sharp & Dohme Ireland (Human Health) Limited, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

Moduret 25 Tablets are manufactured by Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Netherlands.

This leaflet was last revised in March 2015.

This leaflet gives you the most important patient information about Moduret 25. If you have any questions after you have read it, ask your doctor or pharmacist.

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