

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dyazide® 50mg/25mg Tablets Triamterene 50mg and Hydrochlorothiazide 25mg

Read all of this leaflet carefully before you are given 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.

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1. WHAT DYAZIDE TABLETS ARE AND WHAT THEY ARE USED FOR

1. What Dyazide Tablets are and what they are used for

Dyazide Tablets belong to a group of medicines called thiazides, which act as diuretics. They make the kidneys remove water from the body and they have the effect of lowering the blood pressure.

Dyazide Tablets are used to treat mild to moderate high blood pressure and they may be used in combination with other medicines.

They can also be used to treat oedema, which is a build-up of fluid in the body.

This may occur in many situations, for instance during treatment with steroids, or with liver and kidney problems, or with heart failure (when the heart doesn't pump efficiently).

2. Before you take Dyazide Tablets

BEFORE YOU TAKE DYAZIDE TABLETS

You should not be given Dyazide Tablets if you:

- know that you are allergic to triamterene and hydrochlorothiazide or any of the other ingredients of Dyazide Tablets (see section 6 of this leaflet)
- have a serious liver or kidney disorder (your doctor will advise you)
- have high levels of potassium in your blood or high levels of calcium in the blood. Your doctor will advise you
- have disease of the adrenal glands causing weakness, weight loss and a deficiency of hormones in the blood (Addison's disease)
- are taking any potassium supplements, spironolactone, amiloride or medicines known as ACE inhibitors (eg. enalapril, ramipiril, for treating high blood pressure or heart failure)
- have a serious complication of diabetes known as diabetic ketoacidosis
- are a breast feeding mother. Dyazide Tablets should not be given to babies.

Tell your doctor if any of these apply to you before you are given this medicine.

Take special care and tell your doctor if:

- you have diabetes
- you have a problem with your liver or kidneys
- you have difficulty passing water (urine)
- you have gout (often felt as painful joints, especially of the big toe), or have been told that you may get gout
- you are taking other thiazides medicines (e.g. bendroflumethiazide), cardiac glycosides (e.g. digoxin, to treat irregular heartbeats) or non steroidal anti-inflammatory drugs (e.g. ibuprofen, a pain killer) or medicines to reduce your blood pressure
- you suffer from pancreatitis (signs of which include severe stomach or back pain)
- you are taking folate antagonists (used to treat cancer) and are pregnant or have cirrhosis of the liver
- you are getting some laboratory tests done. Dyazide may effect the results of thyroid or parathyroid function tests or folic acid test.

Speak to your doctor if any of these apply to you before you are given this medicine

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. The effects of these medicines may change, especially if you are taking:

- medicines for severe mental illness such as lithium
- antidepressants such as reboxetine, fluoxetine, amitriptyline, citalopram, and also Monoamine Oxidase Inhibitors (MAOIs), e.g. phenelzine
- antipsychotic medicines used to treat schizophrenia (e.g. pimozide, thioridazine, amisulpride, sertindole)
- calcium salts or vitamin D
- corticosteroids used to treat inflammatory conditions such as arthritis or asthma (e.g. prednisolone)
- cytotoxics used to treat cancer e.g. cisplatin
- other “water tablets” (diuretics) such as furosemide, acetazolamide
- the contraceptive pill
- medicines used to treat asthma, e.g. salbutamol, bambuterol, fenoterol, eformoterol, ritodrine, salmeterol or terbutaline
- tacrolimus, ciclosporin used in transplant patients to suppress the immune system
- theophylline (used to treat breathing problems)
- medicines used to treat ulcers e.g. carbenoxolone
- colestyramine and colestipol (used to reduce cholesterol levels) should be taken at least two hours before or after you have taken Dyazide
- medicines used to treat fungal infections such as amphotericin or fluconazole
- medicines for hormone replacement therapy e.g. oestrogens
- medicines to treat diabetes, e.g. metformin, sulphonylureas such as chlorpropamide
- other medicines that treat high blood pressure (e.g. prazosin)
- medicines for pain relief, such as non-steroidal anti-inflammatory drugs (e.g. indometacin)
- muscle relaxants (e.g. baclofen or tizanidine)
- cardiac glycosides (e.g. digoxin, to treat irregular heartbeats).

Do not use potassium supplements, spironolactone, amiloride or ACE inhibitors (e.g. enalapril, ramipril, for treating high blood pressure or heart failure).

If you are already taking one of these medicines, speak to your doctor before you are given Dyazide Tablets.

Pregnancy and breast-feeding

Tell your doctor **before** you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breast-feeding.

Dyazide Tablets should not be used during pregnancy or breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Dyazide Tablets should not affect your ability to drive or use machinery.

Important information about some of the ingredients of Dyazide Tablets

This medicine contains 0.88mg sodium in each tablet. This should be taken into consideration by patients on a controlled sodium (salt) diet.

This medicine also contains sunset yellow (E110) which may cause allergic reactions.

3. HOW TO TAKE DYAZIDE TABLETS

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

Your doctor will decide the best dose for you and may change it depending on how you respond to treatment. You may also be given other medicines.

The usual dose is one tablet each day after breakfast.

Your doctor will give you regular blood tests during treatment.

Do not give Dyazide Tablets to young children or new born babies.

If you take more Dyazide Tablets than you should:

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take your Dyazide Tablets:

If you miss a dose, then take it as soon as you remember unless you are within two hours of your next dose. In this case, take the next dose at the normal time. Do not double the next dose to make up for the forgotten one.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dyazide Tablets can cause side-effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare.

Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other side effects may include:

- feeling sick or being sick, diarrhoea
- feeling weak or dizzy and/or have muscle cramps and headaches
- feeling thirsty or have a dry mouth
- gout (often felt as painful joints, especially of the big toe).

very rarely, some patients may develop a skin rash especially when the skin is exposed to daylight. Some patients may develop a condition known as systemic lupus erythematosus (SLE).

This usually causes inflammation or rheumatoid arthritis-like symptoms (pain, stiffness and/or swelling of the joints) and can occur anywhere in the body

- purple or red brown spots visible through the skin (thrombocytopenic purpura)
 - form of anaemia which results from low levels of folic acid (megaloblastic-anaemia)
 - a fall in the number of white blood cells which can cause frequent infections
 - a more severe decrease in a specific class of white blood cell (agranulocytosis)
 - bleeding or bruising more easily than normal. This can be caused by a fall in the number of small blood cells called platelets
 - increased blood lipid levels
 - high blood glucose levels
 - pneumonitis characterized by cough, fever or difficulty in breathing
 - pulmonary oedema (symptoms of which include pale skin, coughing up blood or difficulty in breathing)
 - certain other side effects such as changes in the blood, levels of chemicals and salts can only be detected by your doctor. To check for this your doctor may occasionally want to do some blood tests
 - low blood pressure
 - jaundice, which causes a yellowing of the skin and whites of the eyes
 - severe pain in the stomach area due to a condition called acute pancreatitis
 - very rarely, kidney failure may occur but this is reversed when treatment is stopped
 - Under certain lights you may also notice a blue fluorescence in your urine.
- If any of the side effects become 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 DYAZIDE TABLETS

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the box after 'Exp'.

The expiry date refers to the last day of that month.

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 Dyazide Tablets contain:

The active substances are 50mg of Triamterene and 25mg of Hydrochlorothiazide.

The other ingredients are Sunset Yellow (E110), sodium laurilsulfate, sodium starch glycolate type A, povidone 30, magnesium stearate and maize starch.

What Dyazide Tablets look like and contents of the pack:

Dyazide Tablets are round, peach tablets with E93 marked on one side.

They are supplied in blister packs of 30 tablets.

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