

PACKAGE LEAFLET: INFORMATION FOR THE USER

TRITAZIDE

2.5mg/12.5mg tablets; 5mg/25mg tablets

RAMIPRIL/HYDROCHLOROTHIAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this 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 •

What is in this leaflet?

1. What TRITAZIDE is and what it is used for
2. Before you take TRITAZIDE
3. How to take TRITAZIDE
4. Possible side effects
5. How to store TRITAZIDE

1. WHAT TRITAZIDE IS AND WHAT IS IT USED FOR

TRITAZIDE is a combination of two medicines called ramipril and hydrochlorothiazide.

Ramipril belongs to a group of medicines called “ACE inhibitors” (Angiotensin Converting Enzyme Inhibitors). It works by:

- Decreasing your body’s production of substances that raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body.

Hydrochlorothiazide belongs to a group of medicines called “thiazide diuretics” or water tablets. It works by increasing the amount of water (urine) you produce. This lowers your blood pressure.

TRITAZIDE is used to treat high blood pressure. The two active substances work together to lower your blood pressure. They are used together when treatment with just one did not work.

2. BEFORE YOU TAKE TRITAZIDE

Do not take TRITAZIDE:

- If you are allergic (hypersensitive) to ramipril, hydrochlorothiazide or any of the other ingredients of TRITAZIDE (see section 6)
- If you are allergic (hypersensitive) to medicines similar to TRITAZIDE (other ACE inhibitors or sulphonamide derived medicines).

Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- If you have ever had a serious allergic reaction called “angioedema”. The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, TRITAZIDE may not be suitable for you
- If you have severe liver problems
- If you have abnormal amounts of salt substances (calcium, potassium, sodium) in your blood □ If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis)
- During the **last 6 months of pregnancy** (see section below on “Pregnancy and breast-feeding”)
- If you are breast-feeding (see section below on “Pregnancy and breast-feeding”)
- If you are taking a blood pressure medicine containing aliskiren and you have diabetes
- If you are taking a blood pressure medicine containing aliskiren and you have kidney problems.

Do not take TRITAZIDE if any of the above apply to you. If you are not sure, talk to your doctor before taking TRITAZIDE.

Take special care with TRITAZIDE

Check with your doctor or pharmacist before taking your medicine:

- If you have heart, liver or kidney problems
- If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis)
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your TRITAZIDE treatment one day beforehand; ask your doctor for advice
- If you have high amounts of potassium in your blood (shown in blood test results)
- You are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly
- If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus
- You must tell your doctor if you think that you are (or might become) pregnant. TRITAZIDE is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see section below on “Pregnancy and breast-feeding”).

Children

TRITAZIDE is not recommended for children and young people under the age of 18 years. This is because the drug has never been used in these age groups.

If any of the above apply to you (or you are not sure), talk to your doctor before taking TRITAZIDE.

Taking TRITAZIDE with 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 (including herbal medicines). This is because TRITAZIDE can affect the way some other medicines work. Also some medicines can affect the way TRITAZIDE works.

Please tell your doctor if you are taking any of the following medicines. They can make TRITAZIDE work less well:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin)
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.

Please tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with TRITAZIDE:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin)
- Medicines which can lower the amount of potassium in your blood. These include medicines for constipation, diuretics (water tablets), amphotericin B (used for fungal infections) and ACTH (used to test if your adrenal glands are working properly)
- Medicines for cancer (chemotherapy)
- Medicines for heart problems, including problems with your heartbeat
- Medicines to stop the rejection of organs after a transplant such as ciclosporin
- Diuretics (water tablets) such as furosemide
- Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts, and heparin (for thinning blood)
- Steroid medicines for inflammation such as prednisolone
- Calcium supplements
- Allopurinol (used to lower the uric acid in your blood)
- Procainamide (for heart rhythm problems)
- Colestyramine (for reducing fat amounts in your blood)
- Carbamazepine (for epilepsy)
- Aliskiren (for high blood pressure).

Please tell your doctor if you are taking any of the following medicines. They may be affected by TRITAZIDE:

- Medicines for diabetes such as oral glucose lowering medicines and insulin. TRITAZIDE may lower your blood sugar amounts. Check your blood sugar amounts closely while taking TRITAZIDE
- Lithium (for mental health problems). TRITAZIDE may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor
- Medicines to relax your muscles
- Quinine (for malaria)
- Medicines that contain iodine, these may be used when you are having a scan or X-ray in hospital
- Penicillin (for infections)
- Medicines to thin the blood that you take by mouth (oral anticoagulants) such as warfarin.

If any of the above apply to you (or you are not sure), talk to your doctor before taking TRITAZIDE.

Tests

Check with your doctor or pharmacist before taking your medicine:

- If you are having a test for parathyroid function. TRITAZIDE might affect the results of the test
- If you are sports person having an anti-doping test. TRITAZIDE might give you a positive result.

Taking TRITAZIDE with food and alcohol

- Drinking alcohol with TRITAZIDE may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking TRITAZIDE, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.
- TRITAZIDE may be taken with or without food.

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant

You should not take TRITAZIDE in the first 12 weeks of pregnancy, and you must not take them at all after the 13th week as their use during pregnancy may possibly be harmful to the baby. If you become pregnant while on TRITAZIDE, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

You should not take TRITAZIDE if you are breast-feeding.

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

Driving and using machines

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

3. HOW TO TAKE TRITAZIDE

Always take TRITAZIDE 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

Treatment of high blood pressure

Your doctor will adjust the amount you take until your blood pressure is controlled.

Elderly Your doctor will reduce the initial dose and adjust your treatment more slowly.

If you take more TRITAZIDE 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. This is so the doctor knows what you have taken.

If you forget to take TRITAZIDE

- If you miss a dose, take your normal dose when it is next due.
- 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, TRITAZIDE can cause side effects, although not everybody gets them.

Stop taking TRITAZIDE and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to TRITAZIDE
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform).

Tell your doctor immediately if you experience:

- Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke
- Shortness of breath, cough fever lasting 2 to 3 days and feeling less hungry. These could be signs of lung problems including inflammation
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots, blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems.
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas)
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

Other side effects include:

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

Common (affects less than 1 in 10 people)

- Headache, feeling weak or tired
- Feeling dizzy. This is more likely to happen when you start taking TRITAZIDE or start taking a higher dose
- Dry tickly cough or bronchitis
- Blood test showing a higher amount of sugar than usual in your blood. If you have diabetes, this may make your diabetes worse
- Blood test showing a higher amount of uric acid or more fat than usual in your blood □
Painful, red, and swollen joints

Uncommon (affects less than 1 in 100 people)

- Skin rash with or without raised area
- Flushing, fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia)
- Loss or change in the way things taste
- Sleep problems
- Feeling depressed, anxious, more nervous or shaky than usual
- Blocked nose, inflammation of your sinuses (sinusitis), shortness of breath
- Inflammation of the gums (gingivitis), swollen mouth
- Red, itchy, swollen or watery eyes
- Ringing in your ears
- Blurred vision

- Hair loss
- Chest pain
- Pain in your muscles
- Constipation, stomach or gut pain
- Indigestion or feeling sick
- Passing more water (urine) than usual over the day
- Sweating more than usual or feeling thirsty
- Loss or decrease of appetite (anorexia), feeling less hungry
- Increased or irregular heartbeat
- Swollen arms and legs. This may be a sign of your body holding onto more water than usual
- Fever
- Sexual inability in men
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin
- Blood tests showing changes in the way your liver, pancreas or kidneys are working □ Blood tests showing less potassium than usual in your blood.

Very rare (affects less than 1 in 10,000 people)

- Being sick, getting diarrhoea or heartburn
- Red swollen tongue or dry mouth
- Blood tests showing more potassium than usual in your blood.

Other side effects reported:

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

- Difficulty concentrating, feeling restless or confused
- Fingers and toes changing colour when cold and then tingling or painful when you warm up. This could be Raynaud's phenomenon
- Breast enlargement in men
- Blood clots
- Disturbed hearing
- Your eyes watering less than usual
- Objects looking yellow
- Dehydration
- Swelling, pain and redness in your cheek (inflammation of a salivary gland)
- A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea
- Being more sensitive to the sun than usual
- Severe flaking or peeling of the skin, itchy, lumpy rash or other skin reactions such as red rash on your face or forehead
- Skin rash or bruising
- Blotches on your skin and cold extremities
- Nail problems (e.g. loosening or separation of a nail from its bed)
- Musculoskeletal rigidity or not being able to move your jaw (tetany)
- Weakness or cramps in your muscles
- Reduced sexual desire in men or women
- Blood in your water (urine). This could be a sign of a kidney problem (interstitial nephritis)
- More sugar than usual in your water (urine)
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing too few blood cells in your blood (pancytopenia)

- Blood tests showing a change in the amount of salts such as sodium, calcium, magnesium and chloride in your blood
- Slowed or impaired reactions
- Change in the way things smell
- Difficulty breathing or worsening of asthma

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

5. HOW TO STORE TRITAZIDE

Keep out of the reach and sight of children.

Do not use TRITAZIDE after the expiry date (EXP) which is stated on the cartons and blisters. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via waste water 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 TRITAZIDE contains

Each tablet 2.5 mg/12.5 mg contains 2.5 mg of ramipril and 12.5 mg of hydrochlorothiazide

Each tablet 5 mg/25 mg contains 5 mg of ramipril and 25 mg of hydrochlorothiazide

The other ingredients are Hypromellose, Pregelatinized maize starch, microcrystalline cellulose, sodium stearyl fumarate and red ferric oxide or E-172 (in the 5 mg/12.5 mg).

What TRITAZIDE looks like and contents of the pack

Tablets 2.5 mg/12.5 mg are white to almost white oblong tablets with score line, both sides embossed with “HNV and company logo”. The tablet can be divided into equal halves.

TRITAZIDE 2.5 mg/12.5 mg tablets are supplied in packs of 10, 14, 18, 20, 28, 30, 45, 50, 56, 60, 98, 99, 100, 300 tablets in PVC/Alu blisters

Tablets 5 mg/25 mg are white to almost white oblong tablets with score line, both sides embossed with “HNW and company logo”). The tablet can be divided into equal halves.

TRITAZIDE 5 mg/25 mg tablets are supplied in packs of 10, 14, 18, 20, 28, 30, 45, 50, 56, 98, 99, 100 300 tablets in PVC/Alu blisters