

## Package leaflet: Information for the user

### Innozide® 20/12.5mg Tablets

(enalapril maleate and hydrochlorothiazide)

#### 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. See section 4.

The name of your medicine is Innozide 20/12.5mg Tablets but will be referred to as Innozide throughout the remainder of the leaflet.

#### What is in this leaflet

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

#### 1. What Innozide is and what it is used for

Innozide contains enalapril maleate and hydrochlorothiazide:

- enalapril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors), which work by widening your blood vessels
- hydrochlorothiazide belongs to a group of medicines known as water tablets (diuretics), which increase the volume of urine you produce.

The effect of these medicines is to lower your blood pressure. Innozide is used to treat high blood pressure (hypertension). Taking both medicines that Innozide contains can increase their effect compared to taking just one.

#### 2. What you need to know before you take Innozide

##### Do not take Innozide:

- if you are allergic to enalapril maleate, hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6)
- if you have previously been treated with a medication in the same group of drugs as this medicine (ACE inhibitors) and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. You should not take this medicine if you have had these types of reactions without a known cause, or if you have been diagnosed with hereditary or idiopathic angioedema
- if you are allergic to any sulfonamide-derived drugs. Ask your doctor if you are not sure what sulfonamide-derived drugs are.
- if you are not passing urine
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are more than 3 months pregnant. It is also better to avoid Innozide in early pregnancy – see pregnancy section
- if you have a condition known as renal artery stenosis (narrowing of the arteries that supply the blood to your kidneys)
- if you have severe kidney or liver problems
- if you are being treated with sacubitril/valsartan, a medicine for heart failure.

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Innozide:

- if 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 Innozide, seek medical attention immediately.
- if you have kidney problems, have had a recent kidney transplantation, are a dialysis patient, or are taking water tablets (diuretics)
- if you have blood disorders or liver problems
- if you are on a salt restricted diet, or have suffered from excessive vomiting or diarrhoea recently
- if you have a heart condition called ‘aortic stenosis’, ‘hypertrophic cardiomyopathy’ or ‘outflow obstruction’
- if you have collagen vascular disease, are taking immunosuppressant therapy (used for the treatment of autoimmune disorders such as rheumatoid arthritis or following transplant surgery)
- if you are taking allopurinol, (used for the treatment of gout), or procainamide, (used to treat abnormal heart rhythms). If you develop an infection (symptoms may be high temperature or fever), you should let your doctor know immediately. Your doctor may take a blood sample from time to time to check your white blood cell count
- if you have a history of ‘angioedema’ while taking other medicines. The signs may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids
- if you have diabetes and are taking antidiabetic medicines, including insulin to control your diabetes (you should monitor your blood for low blood glucose levels, especially during the first month of treatment)
- if you are taking potassium supplements, potassium containing salt substitutes, or other drugs that may increase potassium in your blood (e.g., heparin [a medicine used to prevent blood clots], trimethoprim-containing products such as cotrimoxazole [medicines used to treat infections])
- if you are taking lithium, used for the treatment of some psychiatric illnesses
- if you have been told by your doctor that you have an intolerance to some sugars.
- if you think you are (**or might become**) pregnant. This medicine is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section)
- if 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 Innozide
- tell your doctor if you are taking an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus: medicines used to treat certain types of cancer or to prevent the body’s immune system from rejecting a transplanted organ), a medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan), used in patients with heart failure, or racecadotril, used in patients with acute diarrhoea, or vildagliptin, a medicine used to treat diabetes. You may be at increased risk for an allergic reaction called angioedema
- tell your doctor if you are taking either of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARB) (also known as sartans – for example valsartan, telmisartan, irbesartan etc), in particular if you have diabetes-related kidney problems
  - aliskiren
- tell your doctor if 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 weeks of taking Innozide. 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.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g., potassium) in your blood at regular intervals.

See also information under the heading “Do not take Innozide”.

#### If you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking Innozide:

- any surgery or receive anaesthetics (even at the dentist)
- a treatment called LDL apheresis, to remove cholesterol from your blood using a machine
- desensitisation treatment, to reduce the effect of an allergy to bee or wasp stings.

#### Routine tests

When you first start to take Innozide, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, sodium, magnesium, creatinine and liver enzyme levels. Tell your doctor if you have or will take an anti-doping test since this medication can produce a positive result.

#### Children and adolescents

Innozide is not recommended for use in children.

#### Other medicines and Innozide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. Your doctor may need to change your dose and/or to take other precautions.

In general, Innozide can be taken with other drugs. For prescribing the correct dose of Innozide, it is especially important for your doctor to know whether you are taking any of the following medicines:

- an angiotensin II-receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Innozide” and “Warnings and precautions”),
- potassium sparing water tablets (diuretics) such as spironolactone, eplerenone, triamterene or amiloride, potassium supplements, potassium-containing salt substitutes or other drugs that may increase potassium in your blood (e.g., heparin [a medicine used to prevent blood clots], trimethoprim-containing products such as cotrimoxazole [medicines used to treat infections]). Innozide may increase the levels of potassium in your blood leading to high potassium levels. This causes few signs and is usually seen by a test,
- water tablets (diuretics) such as thiazides, furosemide, bumetanide,
- other medicines that lower blood pressure, such as nitroglycerin, nitrates, and vasodilators,
- lithium, used for the treatment of some psychiatric illnesses. Innozide should not be taken with this drug,
- barbiturates (sedatives used for sleeplessness or epilepsy),
- tricyclic antidepressants such as amitriptyline, used for depression, antipsychotics such as phenothiazines, used for severe anxiety,
- pain killers such as morphine or anaesthetics, because your blood pressure may become too low,
- cholestyramine or colestipol (used to help control cholesterol levels),
- medicines used for, stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
  - including gold therapy which can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with Innozide, and
  - non-steroidal anti-inflammatory drugs (NSAIDs), for example diflunisal or diclofenac. They may prevent your blood pressure from being well controlled and may increase the level of potassium in your blood

- medicines such as ephedrine, used in some cough and cold remedies, or noradrenaline and adrenaline used for low blood pressure, shock, cardiac failure, asthma or allergies. If used with Innozide these drugs may keep your blood pressure high,
- ACTH (to test whether your adrenal glands are working properly),
- corticosteroids (used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders),
- allopurinol (used to treat gout),
- ciclosporins (immunosuppressive agents used for autoimmune disorders),
- medicines for the treatment of cancer,
- procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms),
- digitalis (used to treat heart rhythm problems),
- carbenoxalone (used to treat stomach ulcers),
- excessive use of laxatives,
- antidiabetic medicines such as insulin. Innozide may cause your blood sugar levels to drop even further if you take it with antidiabetics,
- an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines used to treat certain types of cancer or to prevent the body’s immune system from rejecting a transplanted organ). See also information under the heading “Warnings and precautions”,
- a medicine containing a neprilysin inhibitor such as sacubitril (available as fixeddose combination with valsartan), or racecadotril, or a medicine containing vildagliptin. The risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased. See also information under the headings “Do not take Innozide” and “Warnings and precautions”.

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

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

Most people take Innozide with a drink of water.

Innozide can be taken with or without food. However, if you drink alcohol while taking Innozide, it may cause your blood pressure to drop too much and you may experience dizziness, light-headedness or faintness. You should keep your alcohol intake to a minimum.

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

##### Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Innozide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Innozide. This medicine is not recommended during pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

##### Breast-feeding

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

#### **Driving and using machines**

Side effects of this medicine include blurred vision, feeling dizzy, feeling drowsy, or confused (see Possible side effects). If this happens do not drive or use any tools or machines.

#### **Innozide contains lactose**

Innozide contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### **Innozide contains sodium**

Innozide contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

### 3. How to take Innozide

#### Taking this medicine

- You should take this medicine by mouth.
- Always take this medicine exactly as your doctor or pharmacist has told you.
- The number of tablets you take each day will depend upon your condition.

Check with your doctor or pharmacist if you are not sure.

REMEMBER, this medicine is for you. Do not share it with anyone else. It may not suit them.

The recommended dose is:

- One tablet each day.
- Your doctor may increase the dose to two tablets each day.
- Do not take more or less than your doctor has prescribed.

Your medicine is available in a days of the week blister, a translation of the days of the week are below:

Lun	Mar	Mié	Jue	Vie	Sáb	Dom
Mon	Tue	Wed	Thu	Fri	Sat	Sun

#### If you take more Innozide than you should

Contact your doctor immediately if you think you have taken more of your tablets than you should. The most common signs and symptoms of an overdose are a fall in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or light-headedness due to a fall in blood pressure, forceful and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

#### If you forget to take Innozide

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Innozide

Do not stop taking your medicine, unless your doctor tells you to. If you do your blood pressure may increase. If your blood pressure becomes too high, it may affect your heart and kidneys. 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:

#### It is vital to stop taking Innozide and seek medical attention immediately if you begin to have the following symptom:

- allergic reaction - you may get a rash, short of breath or wheezy and develop swelling of your hands, mouth, throat, face or eyes.
- severe hypersensitivity reaction with high fever, skin rash that looks like targets (erythema multiforme); severe skin conditions with reddening, scaling and blistering of the skin (Stevens Johnson syndrome and toxic epidermal necrolysis).
- Liver failure or hepatitis. This may cause yellowing of your skin (jaundice).

#### Stop taking Innozide immediately and see your doctor if you have any of the following side effects

- severe dizziness, light-headedness, especially at the start of treatment or when your dose is increased or when you stand up.

Other possible side effects

**Very common** (may affect more than 1 in 10 people):

- blurred vision, cough, feeling sick (nausea), weakness

**Common** (may affect up to 1 in 10 people):

- low blood pressure (which may make you feel dizzy or light-headed, especially if you stand up quickly)
- headache, depression, fainting (syncope)
- chest pain, heart rhythm changes, angina or chest pain, fast heart beat, shortness of breath

- diarrhoea, pain around your stomach area (abdomen), changes in taste, fluid retention (oedema), feeling tired
- increased blood potassium level, increases in serum creatinine (both are usually detected by a test); low levels of potassium in the blood, increased levels of cholesterol, increased levels of triglycerides, increased levels of uric acid in the blood
- muscle cramps

**Uncommon** (may affect up to 1 in 100 people):

- decreased number of red blood cells and low haemoglobin (anaemia) a sense of heightened awareness or a shaky feeling (caused by low blood sugar), confusion, feeling sleepy, difficulty sleeping, feeling nervous, tingling or numbness, feeling like you are spinning (vertigo)
- fast or uneven heart beats (palpitations), heart attack or stroke (in high risk patients)
- runny nose, sore throat and hoarseness, difficulty breathing or asthma
- slow movement of food through your intestine (ileus), inflammation of the pancreas (pancreatitis), being sick, indigestion, constipation, not feeling like eating properly (anorexia), stomach irritation, dry mouth, flatulence, gout
- burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a peptic ulcer), increased sweating, itching, hives (urticaria), hair loss, protein in your urine (usually detected by a test)
- impotence, decreased libido, flushing, ringing in your ears, feeling lethargic, high temperature
- increases in blood urea and decreases in blood sodium levels (usually detected by a test), feeling unwell (malaise)
- low level of magnesium in the blood (hypomagnesaemia)
- kidney problems
- joint pain

**Rare** (may affect up to 1 in 1,000 people):

- strange dreams, sleep problems
- changes in blood test values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, and/or swollen glands in neck, armpit or groin
- autoimmune diseases, low blood flow to your fingers and toes causing redness and pain (Raynaud's), accumulation of fluid or other substances in the lungs (as seen on X-rays), runny or sore nose
- eosinophilic pneumonia (signs may be cough, high temperature and difficulty breathing)
- pain, swelling or ulcers in your mouth, infection or pain and swelling of your tongue, kidney problems such as lower back pain and reduction in the volume of urine you pass
- inflammation of the nose
- difficulty breathing, shortness of breath
- gall bladder problems
- severe skin rash with loss of skin and hair (exfoliative dermatitis), cutaneous lupus erythematosus (an immune disease), red rash with peeling of the skin (erythroderma), small fluid-filled bumps on the skin (pemphigus), purple or red spots on the skin (purpura)
- development of breasts in men
- increased liver enzymes or blood 'bilirubin' (usually detected by a blood test), increases in blood sugar
- muscle weakness, sometimes due to low potassium (paresis)

**Very rare** (may affect up to 1 in 10,000 people):

- swelling in your intestine (intestinal angioedema). Signs may include stomach pain, feeling sick and vomiting, elevated calcium level in blood
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

**Not known** (frequency cannot be estimated from the available data):

A complex side effect has also been reported which may include some or all of the following signs:

- fever, inflammation of your blood vessels, pain and inflammation of muscles or joints
- blood disorders affecting the components of your blood (usually detected by a blood test)
- rash, hypersensitivity to sunlight and other effects on your skin
- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion
- 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)).

#### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store Innozide

#### Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not take them past the expiry date which is clearly marked on the pack. The expiry date refers to the last day of the 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.

If your medicine shows any signs of discolouration or deterioration consult your pharmacist for advice. If damaged, please tell your doctor or pharmacist.

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

Innozide is available as biconvex, hexagonal, yellow, scored and debossed with 'MSD 718' on one side. The score serves only to break the tablet and facilitate swallowing but not to divide into equal doses.

The active ingredients in Innozide are enalapril maleate and hydrochlorothiazide. Each tablet contains 20 mg enalapril maleate and 12.5 mg hydrochlorothiazide.

Also contains: sodium hydrogen carbonate, lactose monohydrate, maize starch, yellow ferric oxide E172, pregelatinised starch, magnesium stearate.

Innozide Tablets are available in blister packs containing 28 tablets.

Manufactured by: Merck Sharp & Dohme, B.V. Waarderweg 39, 2031 BN Haarlem, The Netherlands or Frosst Iberica, S.A. Via Complutense, 140. 28805- Alcala de Henares (Madrid) Spain or Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

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**POM**

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## Blind or partially sighted?

## Is this leaflet hard to see or read?

## Contact Quadrant Pharmaceuticals

Ltd, Tel: 01204 471 269