

## Package leaflet: Information for the user

### **INNOZIDE® 20 mg/12.5 mg Tablets** enalapril maleate/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 want 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 symptoms 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.

#### **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 known as 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 have ever had an allergic reaction to Innozide, a similar medicine or to any of the ingredients (listed in Section 6). The signs may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids
- you are allergic to a type of medicine called ‘sulphonamides’
- you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited
- you are more than 3 months pregnant (it is also better to avoid Innozide in early pregnancy – see pregnancy section)
- you are breast-feeding
- you are not passing urine

- you have a condition known as renal artery stenosis (narrowing of the arteries that supply the blood to your kidneys)
- you have severe kidney or liver problems
- you have a condition known as 'hyperkalaemia' due to high levels of potassium in your blood
- you have a heart condition called 'aortic stenosis', 'hypertrophic cardiomyopathy' or 'outflow obstruction'
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

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

Whilst a combination of an enalapril tablet and a hydrochlorothiazide tablet is often used for congestive heart failure, Innozide is not recommended for this purpose.

### **Warnings and precautions**

#### **Check with your doctor or pharmacist before taking Innozide if:**

- you have kidney problems, have had a recent kidney transplantation, are a dialysis patient, or are taking water tablets (diuretics)
- you have blood disorders or liver problems
- you are on a salt restricted diet, or have suffered from excessive vomiting or diarrhoea recently
- you have a heart condition called 'aortic stenosis', 'hypertrophic cardiomyopathy' or 'outflow obstruction'
- you have collagen vascular disease, are taking immunosuppressant therapy (used for the treatment of autoimmune disorders such as rheumatoid arthritis or following transplant surgery)
- 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
- 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)
- you are taking potassium supplements, potassium-sparing agents, 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])
- you are taking lithium, used for the treatment of some psychiatric illnesses
- you have been told by your doctor that you have an intolerance to some sugars.
- if you are taking any of the following medicines, the risk of angioedema may be increased:
  - Racecadotril, a medicine used to treat diarrhoea.
  - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).

–Vildagliptin, a medicine used to treat diabetes.

- you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly longterm 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.
- you are taking any 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
- 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.

You must tell your doctor if you think you are (or might become) pregnant. Innozide 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 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**

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”

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**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription as some drugs may affect each other's action. Your doctor may need to change your dose and/or to take other precautions. This includes herbal medicines. Also some other medicines can affect the way Innozide work:

- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Innozide if” and “Warnings and Precautions”)

- potassium sparing water tablets (diuretics) such as spironolactone, eplerenone, triamterene or amiloride, potassium supplements, or potassium-containing salt substitutes. 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
- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots). See also information under the heading “Warnings and precautions”.water tablets (diuretics) such as thiazides, furosemide, bumetanide
- other medicines that lower blood pressure, such as nitroglycerine, 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
- Antacids (used for indigestion relief)
- 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 fixed-dose combination with valsartan), racecadotril or 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 and drink**

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. If this happens to you, then you should avoid drinking alcohol.

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

##### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. 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. Innozide 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. Innozide is not recommended for mothers who are breast-feeding.

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

**Certain side effects, such as dizziness and weariness, have been reported with Innozide.** If this happens to you, avoid activities which require alertness; for example, driving a car or operating machinery (see Possible side effects).

##### **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 medicinal product.

##### **Innozide contains sodium**

This medicine 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 Innozide exactly as your doctor told you.
  - The number of tablets you take each day will depend upon your condition.
- You should 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 usual dose for many people 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.

### **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 has told 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 product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines Innozide 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 symptoms:**

-allergic reaction- you may get an itch, shortness of breath or wheezing and develop swelling of your hands, mouth, throat, face or eyes. If you are a black person, you should be aware that black patients are more likely to suffer from these types of reactions.

**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** (affects more than 1 in 10 people)

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

**Common** (affects less than 1 in 10 people)

- headache, depression, low blood pressure, fainting (syncope)
- angina or chest pain, heart rhythm changes, fast or uneven heart beat (palpitations), shortness of breath
- diarrhoea, pain around your stomach area (abdomen), changes in taste, fluid retention (oedema), feeling tired
- rash, hypersensitivity/angioneurotic oedema: angioneurotic oedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported.
- 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** (affects less than 1 in 100 people)

- anaemia (including aplastic and haemolytic), anxiety, 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)
- low blood pressure (which may make you feel dizzy when you stand up), racing or uneven heart beats, heart attack or stroke (in high risk patients)
- runny nose, sore throat and hoarseness, difficulty breathing or asthma
- a blockage or slow movement of food through your intestine (ileus), 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), excessive 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), weakness (malaise)
- low level of magnesium in the blood (hypomagnesemia)
- kidney problems
- joint pain

**Rare** (affects less than 1 in 1,000 people)

- strange dreams, sleeping problems
- decreases in your white blood cells, red blood cells, haemoglobin, platelets, bone marrow depression (all are usually detected by tests)
- swollen glands in neck, armpit or groin, autoimmune diseases, low blood flow to your fingers and toes causing redness and pain (Raynaud's), fluid on your lungs, 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, accumulation of fluid or other substances in the lungs (as seen on X-rays) difficulty breathing, respiratory distress

- liver failure or hepatitis, this may cause yellowing of your skin (jaundice), gallbladder problems
- severe hypersensitivity reaction with high fever, skin rash that looks like targets (erythema multiforme), Stevens-Johnson syndrome and toxic epidermal necrolysis (severe skin conditions with reddening, scaling and blistering of the skin), 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** (affects less than 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

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

- Skin and lip cancer (non-melanoma skin cancer)

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
- 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))

If any of these 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 HPRC Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Innozide**

Keep your tablets out of the reach and sight of children.

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

Do not put them into another container as they might get mixed up.

Do not use this medicine after the expiry date which is stated on the carton 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. Contents of the pack and other Information**

### **What Innozide contains:**

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

The other ingredients in Innozide are sodium hydrogen carbonate E500, lactose, maize starch, yellow ferric oxide E172, pregelatinised starch, magnesium stearate E572.

### **What Innozide looks like and the contents of the pack**

Innozide is available as round, fluted, yellow tablets with 'MSD 718' on one side and scored on the other.

Innozide Tablets are available in blister packs containing 28 tablets.

### **Marketing Authorisation Holder and Manufacturer**

Organon Pharma (Ireland) Limited  
2 Dublin Landings, North Wall Quay - North Dock  
Dublin, D01 V4A3, Ireland.

Your tablets are made by Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium.

This leaflet was last revised in November 2022.

This leaflet gives you some of the most important patient information about Innozide. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.

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