**Package leaflet: Information for the user**

# Valsartan/Hydrochloorthiazide Viatris 80 mg/12.5 mg, filmomhulde tabletten
# Valsartan/Hydrochloorthiazide Viatris 160 mg/12.5 mg, filmomhulde tabletten
# Valsartan/Hydrochloorthiazide Viatris 160 mg/25 mg, filmomhulde tabletten
# Valsartan/Hydrochloorthiazide Viatris 320 mg/12.5 mg, filmomhulde tabletten
# Valsartan/Hydrochloorthiazide Viatris 320 mg/25 mg, filmomhulde tabletten

valsartan/hydrochloorthiazide

**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.

**What is in this leaflet**


## 1. What Valsartan/Hydrochloorthiazide Viatris is and what it is used for

Valsartan/Hydrochloorthiazide Viatris film-coated tablets contain two medicines called valsartan and hydrochlorothiazide. Both of these medicines help to control high blood pressure (hypertension).

- **Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

- **Hydrochlorothiazide** belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

Valsartan/Hydrochloorthiazide Viatris is used to treat high blood pressure which is not controlled by a single medicine alone.

High blood pressure increases the workload of the heart and arteries. If not treated, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

## 2. What you need to know before you take Valsartan/Hydrochloorthiazide Viatris

### Do not take Valsartan/Hydrochloorthiazide Viatris

- if you are **allergic** to valsartan, hydrochlorothiazide, sulfonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of this medicine (listed in section 6).
- if you are **more than 3 months pregnant.** (It is also better to avoid Valsartan/Hydrochloorthiazide Viatris in early pregnancy - see pregnancy section).
- if you have severe liver disease.
- if you have severe kidney disease.
- if you are unable to urinate.
- if you are treated with an artificial kidney.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.
- if you have gout.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, do not take this medicine and talk to your doctor.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan/Hydrochloorthiazide Viatris:
- 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 Valsartan/Hydrochloorthiazide Viatris, seek medical attention immediately.
- 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 Valsartan/Hydrochloorthiazide Viatris.
- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have a history of sulfonamide or penicillin allergy.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- if you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of Valsartan/Hydrochloorthiazide Viatris is not recommended.
- if you have liver or kidney disease.
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or fats in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering agents of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- it may cause increased sensitivity of the skin to sun.
- you must tell your doctor if you think you are (or might become) pregnant. Valsartan/Hydrochloorthiazide Viatris 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 taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren.

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 Valsartan/Hydrochloorthiazide Viatris".

- 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 Valsartan/Hydrochloorthiazide Viatris. 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.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Valsartan/Hydrochloorthiazide Mylan. Your doctor will decide on further treatment. Do not stop taking Valsartan/Hydrochloorthiazide Mylan on your own.

**Children and adolescents**

Valsartan/Hydrochloorthiazide Viatris is not recommended in children and adolescents below the age of 18 years.

**Other medicines and Valsartan/Hydrochloorthiazide Viatris**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effectiveness of this medicine can be influenced if taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:

- lithium, a medicine used to treat some types of psychiatric illness
- medicines that affect or can be affected by potassium blood levels, such as digoxin, a medicine to control the heart rhythm, some antipsychotic and antidepressant medicines
- medicines that may increase the amount of potassium in your blood, such as potassium supplements, potassium-containing salt substitutes, potassium sparing medicines, heparin
- medicines that may reduce the amount of potassium in your blood, such as corticosteroids, some laxatives
- diuretics (water tablets), medicines for the treatment of gout, such as allopurinol, therapeutic vitamin D and calcium supplements, medicines for the treatment of diabetes (oral agents or insulin)
- other medicines to lower your blood pressure, such as beta-blockers or methyldopa, or medicines that tighten your blood vessels or stimulate your heart, such as noradrenaline or adrenaline
- medicines to increase blood sugar levels, such as diazoxide
- medicines to treat cancer, such as methotrexate or cyclophosphamide
- pain killers
- arthritis medicines
- muscle relaxing medicines, such as tubocurarine
- anti-cholinergic medicines, such as atropine or biperiden

- amantadine (a medicine used to prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of fats in the blood)
- ciclosporin, a medicine used for organ transplant to avoid organ rejection
- barbiturates and narcotics (medicines with sleeping or painkiller effect used during surgery for example)
- antiepileptics such as carbamazepine, a medicine used to treat seizure conditions
- rifampin, a medicine used to treat tuberculosis
- ritonavir, a medicine used to treat HIV infection
- medicines affecting gastric motility, such as cisapride
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Valsartan/Hydrochloorthiazide Viatris" and "Warnings and precautions")

**Valsartan/Hydrochloorthiazide Viatris with food, drink and alcohol**

You can take Valsartan/Hydrochloorthiazide Viatris with or without food.
Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

**Pregnancy and breast-feeding**

Pregnancy
If you are pregnant, 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 Valsartan/Hydrochloorthiazide Viatris before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan/Hydrochloorthiazide Viatris. Valsartan/Hydrochloorthiazide Viatris is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

Breast-feeding
If you are breast-feeding or about to start breast-feeding, ask your doctor for advice before taking this medicine. Valsartan/Hydrochloorthiazide Viatris is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how Valsartan/Hydrochloorthiazide Viatris affects you. Like many other medicines used to treat high blood pressure, Valsartan/Hydrochloorthiazide Viatris may occasionally cause dizziness and affect the ability to concentrate.

**Valsartan/Hydrochloorthiazide Viatris contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Valsartan/Hydrochloorthiazide Viatris

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Valsartan/Hydrochloorthiazide Viatris is one tablet per day. The medicine should be taken at the same time each day, usually in the morning. Your doctor will tell you exactly how many tablets of Valsartan/Hydrochloorthiazide Viatris to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

You may find this medicine has an unusual odour and/or taste. This is normal and characteristic of the active substance valsartan.

**Use in children**

Valsartan/Hydrochlorothiazide is not recommended for children and adolescents below the age of 18 years.

**Route and method of administration**

You can take this medicine with or without food. Swallow the tablet with a glass of water.

**Duration of treatment**

Do not change the dose or stop taking the tablets without consulting your doctor. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with your doctor even if you are feeling well.

**If you take more Valsartan/Hydrochloorthiazide Viatris than you should**

If you experience severe dizziness and/or fainting, lie down and contact your doctor immediately. If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital emergency department.

**If you forget to take Valsartan/Hydrochloorthiazide Viatris**

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Valsartan/Hydrochloorthiazide Viatris**

Stopping your treatment with Valsartan/Hydrochloorthiazide Viatris may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to stop.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious and may need immediate medical attention. Tell your doctor immediately or go to the hospital casualty department if you experience symptoms of angioedema, such as:
- swollen face, tongue or pharynx

- difficulty in swallowing
- hives and difficulties in breathing
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme)

The following side effects have been observed during treatment with Valsartan/Hydrochloorthiazide Viatris with the following frequencies:

**Uncommon side effects: may affect up to 1 in 100 people**
- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark coloured urine or dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises in ears such as hissing or buzzing

**Very rare side effects: may affect up to 1 in 10,000 people**
- dizziness
- diarrhoea
- joint pain

**Not known: frequency cannot be estimated from the available data**
- breathing difficulty
- severely decreased urine output
- low level of sodium in the blood (sometimes with nausea, tiredness, confusion, malaise, convulsions)
- low level of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm)
- low level of white cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness)
- increased level of bilirubin in blood (which can, in severe cases, trigger yellow skin and eyes)
- increased level of blood urea nitrogen and creatinine in blood (which can indicate abnormal kidney function)
- increased level of uric acid in blood (which can, in severe cases, can trigger gout)
- syncope (fainting)

**Side effects of valsartan or hydrochlorothiazide alone but not observed with Valsartan/Hydrochloorthiazide Viatris**

**Valsartan**

**Uncommon side effects: may affect up to 1 in 100 people**
- spinning sensation
- abdominal pain

**Very rare side effects: may affect up to 1 in 10 000 people**
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

**Not known: frequency cannot be estimated from the available data**
- blistering skin (sign of dermatitis bullous)
- skin rash with or without itching together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms
- rash, purplished-red spots, fever, itching (symptoms of inflammation of blood vessels)
- low level of blood platelets (sometimes with unusual bleeding or bruising)
- high level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness)
- swelling mainly of the face and throat; rash; itching
- elevation of liver function values
- decreased level of haemoglobin and decreased percentage of red cells in the blood (which both can, in severe cases, trigger an anaemia).
- kidney failure

**Hydrochlorothiazide**

**Very common: may affect more than 1 in 10 people**
- low blood levels of potassium, blood lipids increased (mainly at higher doses)

**Common side effects: may affect up to 1 in 10 people**
- itchy rash and other types of rash
- low blood levels of sodium, low blood levels of magnesium
- high levels of uric acid
- reduced appetite
- mild nausea and vomiting
- faintness, fainting on standing up
- impotence

**Rare side effects: may affect up to 1 in 1,000 people**
- swelling and blistering of the skin (due to increased sensitivity to sun)
- constipation, discomfort of the stomach or bowels, liver disorders (yellow skin or eyes)
- irregular heart beat
- high levels of calcium, high level of blood sugar , excretion of sugar in the urine, worsening of diabetic metabolic state
- headache, dizziness, tingling or numbness in the hands and feet
- sleep disturbances
- sad mood (depression)
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin)
- dizziness, tingling or numbness in the hands and feet.

**Very rare side effects: may affect up to 1 in 10,000 people**
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever
- itching or red skin
- blistering of the lips, eyes or mouth
- skin peeling
- fever
- facial rash associated with joint pain
- muscle disorder
- fever (cutaneous lupus erythematosus)
- severe upper stomach pain; lack or low levels of different blood cells
- severe allergic reactions

- difficulty breathing
- lung infection; breathlessness
- a metabolic disorder resulting in a loss of chloride from the body
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

**Not known: frequency cannot be estimated from the available data**
- severe reduction in blood cells which can cause weakness, bruising or make infections more likely
- 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) or acute angle-closure glaucoma).
- kidney dysfunction, acute kidney failure
- fever, weakness
- muscle spasm
- skin and lip cancer (non-melanoma skin cancer).

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Valsartan/Hydrochloorthiazide Viatris

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, label, blister or bottle after EXP. The expiry date refers to the last day of that month.

Use within 3 months of opening of opening the bottle. Once open keep bottle tightly closed.

This medicinal product does not require any special storage conditions. Do not use any Valsartan/Hydrochloorthiazide Viatris pack that is damaged or shows signs of tampering.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Valsartan/Hydrochloorthiazide Viatris contains**

The active substances are valsartan and hydrochlorothiazide.

Each 80 mg/12.5 mg tablet contains 80 mg valsartan and 12.5 mg hydrochlorothiazide.

Each 160 mg/12.5 mg tablet contains 160 mg valsartan and 12.5 mg hydrochlorothiazide.

Each 160 mg/25 mg tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide.

Each 320 mg/12.5 mg tablet contains 320 mg valsartan and 12.5 mg hydrochlorothiazide.

Each 320 mg/25 mg tablet contains 320 mg valsartan and 25 mg hydrochlorothiazide.

The other ingredients are: silica colloidal anhydrous, magnesium stearate, sodium lauryl sulfate, cellulose microcrystalline, pregelatinised maize starch, lactose monohydrate, crospovidone, povidone and magnesium stearate. See section 2 'Valsartan/Hydrochloorthiazide Viatris contains lactose and sodium'.

The film-coating contains hypromellose, titanium dioxide (E171), macrogol, talc, vanillin and iron oxide (E172).

**What Valsartan/Hydrochloorthiazide Viatris looks like and contents of the pack**

Valsartan/Hydrochloorthiazide Viatris 80 mg/12.5 mg are peach, oval shaped film-coated tablets engraved with 'VH1' on one side of the tablet and 'M' on other side.

Valsartan/Hydrochloorthiazide Viatris 160 mg/12.5 mg are reddish, oval shaped film-coated tablets engraved with 'VH2' on one side of the tablet and 'M' on other side.

Valsartan/Hydrochloorthiazide Viatris 160 mg/25 mg tablets are brown, oval shaped film-coated tablets engraved with 'VH3' on one side of the tablet and 'M' on other side.

Valsartan/Hydrochloorthiazide Viatris 320 mg/12.5 mg are pink, oval, film-coated tablets marked with 'VH4' on one side of the tablet and 'M' on other side.

Valsartan/Hydrochloorthiazide Viatris 320 mg/25 mg are yellow, oval, film-coated tablets marked with 'VH5' on one side of the tablet and 'M' on other side.

Valsartan/Hydrochloorthiazide Viatris is available in blisters of 28 tablets.

Not all pack sizes may be marketed.

Dit middel is ingeschreven in het register onder de volgende registratienummers: RVG 109818 (80 mg/12,5 mg), RVG 109819 (160 mg/12,5 mg), RVG 109820 (160 mg/25 mg), RVG 112837 (320 mg/12,5 mg), RVG 112838 (320 mg/25 mg).

**Marketing Authorisation Holder and Manufacturer**
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Voor informatie en inlichtingen:
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Hongarije

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| Italië | Valsartan e Idroclorotiazide Mylan |
| Nederland | Valsartan/Hydrochloorthiazide Viatris |

**Deze bijsluiter is voor het laatst goedgekeurd in januari 2025.**