

Package leaflet: Information for the patient

Karvedilol Viatris 3.125 mg, 6.25 mg, 12.5 mg and 25 mg Film-coated Tablets (carvedilol)

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.

In this leaflet:

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

1. What Karvedilol Viatris is and what it is used for

Karvedilol Viatris contains the active ingredient carvedilol which is a beta blocker and vasodilator. Carvedilol widens blood vessels, lowers blood pressure and reduces the effort needed for the heart to pump blood around the body.

Karvedilol Viatris is used to treat high blood pressure and angina (chest pain). Karvedilol Viatris can also be given, along with other medicine, to help treat moderate to severe heart failure.

2. What you need to know before you take Karvedilol Viatris

Do not take Karvedilol Viatris:

- if you are allergic to carvedilol or any of the other ingredients of this medicine (listed in section 6)
- if you have asthma or breathing problems due to other lung problems.
- if you have unstable heart failure or a conduction defect of the heart (so-called AV-block of type II or III unless you have a pacemaker in place, or so-called sick sinus node)
- if you are suffering from a severe heart condition called cardiogenic shock
- if you have a very slow heart beat (less than 50 beats per minute) or very low blood pressure
- if you have liver disease

Warnings and precautions

Talk to your doctor or pharmacist before taking Karvedilol Viatris:

- if you have heart failure and also
 - low blood pressure
 - fluid retention (swelling)
 - not enough blood supply to your heart (ischaemic heart disease)
 - and/or kidney problems

Your doctor will monitor your kidney function. It may be necessary to reduce your dose.

- if you have a conduction problem of the heart known as AV-block type I
- if you have diabetes. Treatment with Karvedilol Viatriis may mask the signs of low blood sugar such as feeling sick, sweating and weakness. Monitor your blood sugar regularly.
- if you have breathing problems, such as breathlessness or wheezing, and you are not taking medicine for it. Karvedilol Viatriis may worsen these breathing difficulties.
- if you wear contact lenses as Karvedilol Viatriis can cause dry eyes
- if you have Raynaud's phenomenon (cold hands and feet) or other **peripheral vascular disease** e.g. blood circulation problems in your legs causing cramp-like pain when you walk, as Karvedilol Viatriis may worsen your symptoms
- if you have an overactive thyroid gland as Karvedilol Viatriis may hide your symptoms
- if you have ever had a serious allergic reaction (e.g. to an insect bite or food) or if you are having allergic desensitisation therapy
- if you have psoriasis.
- If you are suffering from a serious disturbance in the body's acid-balance a condition called metabolic acidosis which causes dehydration, rapid breathing, drowsiness and confusion.
- if you have a **very low pulse** (especially if it is less than 55 beats per minute).
- if you have an **over-function of the adrenal glands** (phaeochromocytoma).
- if you suffer from a particular form of angina pectoris called **Prinzmetal's variant angina** caused by cramping of coronary arteries.
- if you have **labile or secondary hypertension** (your blood pressure fluctuates rapidly or high blood pressure is caused by another medical condition).
- if you suffer from **orthostatic hypotension**, a sudden fall of blood pressure when you stand up.
- if you have **acute inflammatory heart disease**.
- if you have **obstruction of heart valves**.

Other medicines and Karvedilol Viatriis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines, especially any of the following:

- * other medicines for your heart or blood pressure including alpha-blockers (e.g. doxazosin), calcium channel blockers (e.g. verapamil, diltiazem), medicine for an irregular heart rhythm (e.g. quinidine, flecainide, amiodarone), nitrates (e.g. isosorbide mononitrate), digoxin, reserpine
- * other medicine which can cause lowering of blood pressure as a side effect; as carvedilol may worsen this effect e.g. barbiturates (for epilepsy)
- * carbamazepine, to treat epilepsy
- * cinacalcet, to treat high blood levels of calcium
- * bupropion, to treat nicotine addiction
- * fluconazole, to treat fungal infections
- * clonidine, for high blood pressure or migraines; if stopping treatment, Karvedilol Viatriis treatment should be stopped a few days before slowly reducing the clonidine dose
- * antibiotics such as rifampicin, erythromycin
- * cimetidine, to treat stomach ulcers, heartburn
- * ciclosporin, an immunosuppressant used after organ transplants
- * antidepressants (to treat depression) such as monoamine oxidase inhibitors (**MAOIs** e.g. phenelzine), paroxetine, fluoxetine, amitriptyline
- * all types of antidiabetic medicine, including insulin, as carvedilol can increase the effect of these medicines as well as hide the symptoms of low blood sugar (feeling sick, weak and sweating)
- * medicines known as sympathomimetics such as pseudoephedrine (to treat colds), adrenaline (epinephrine) and isoprenaline (heart stimulants), noradrenaline (norepinephrine)
- * neuromuscular blocking medicine (to reduce muscle tension)
- * medicines for breathing problems e.g. salbutamol, formoterol
- * ergotamine, for migraine
- * certain painkillers (NSAIDs) e.g. ibuprofen

- * oestrogens (hormones)
- * corticosteroids e.g. prednisolone.

Surgery

Karvedilol Viatris can react with anaesthetics during surgery. If you are due to have any kind of surgery, including dentistry, tell your doctor or dentist you are taking Karvedilol Viatris.

Ask your doctor for advice before taking any medicine.

Karvedilol Viatris with alcohol

Alcohol may increase the effects of Karvedilol Viatris causing side effects such as dizziness.

Pregnancy and breast-feeding

Beta-blockers may affect the growth of your unborn baby. Carvedilol should only be used during pregnancy if the benefits to the mother outweigh the risk of harm to the baby.

Mothers taking carvedilol should not breast-feed as carvedilol can pass into breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Karvedilol Viatris does not usually affect your ability to drive or use machines. However, some people may suffer side effects such as dizziness or feeling less alert, often at the start of treatment or if the dose is changed. If you suffer from side effects do not drive or use machines and tell your doctor.

Karvedilol Viatris contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Karvedilol Viatris

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

- Swallow the tablets with at least half a glass of water
- You can take the tablets with or without food, however patients with heart failure should take the tablets with food to reduce the risk of dizziness when suddenly standing up
- If you feel the effects are too strong or weak, talk to your doctor.

Karvedilol Viatris Film-coated Tablets are available in different strengths. Your doctor will give you the most suitable strength for your treatment. The 6.25 mg, 12.5 mg and 25 mg tablets can be divided into two equal doses.

Adults (including the elderly)

To treat high blood pressure

The recommended starting dose is 12.5 mg taken once a day for the first 2 days, then 25 mg once a day. If necessary the dose may be increased to a maximum of 50 mg daily, in either one or two doses.

If you are elderly, your doctor may increase the dose more slowly.

Angina

The recommended starting dose is 12.5 mg taken twice a day for the first 2 days, then 25 mg twice a day. If needed your doctor may decide to slowly increase the dose further, to the maximum of 100 mg. The recommended maximum dose for elderly patients is 25 mg twice a day.

Heart failure

The recommended starting dose is 3.125 mg twice a day for two weeks. Your doctor may decide to increase your dose in stages every 2 weeks until the dose is right for you. The maximum

recommended dose is between 25 mg and 50 mg twice a day, depending on your weight. The maximum recommended dose in severe heart failure is 25 mg twice a day.

If carvedilol treatment is stopped for more than two weeks, the dose should be restarted at 3.125 mg twice daily and slowly increased as above.

If you have liver problems your doctor may give you a lower dose than those stated above.

Use in children and adolescents

Karvedilol Viatris should not be given to children or adolescents under 18 years of age.

If you take more Karvedilol Viatris than you should

If you take more Karvedilol Viatris than you should, contact your doctor or casualty department immediately. **Signs of overdose** include feeling faint due to very low blood pressure, a slow heart beat, and in some cases missed heart beats, breathing problems, feeling generally unwell, losing consciousness and fits.

If you forget to take Karvedilol Viatris

If you forget to take a dose of Karvedilol Viatris take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Karvedilol Viatris

If you suddenly stop taking Karvedilol Viatris you are likely to suffer from side effects. If needed your doctor will reduce your treatment slowly.

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.

If you think you may have any of the following side effects contact your doctor or go to your nearest hospital emergency room immediately:

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

- Problems with your heart. The signs include chest pains, tiredness, shortness of breath and swelling of your arms and legs (heart failure or angina).

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

- Severe breathing difficulties, including when resting (pneumonia)
- Serious problems with your kidneys that may cause you to urinate less, feel drowsy or sick, breathless or weak or lose your appetite

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

- Irregular or missed heart beats

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

- Allergic (hypersensitivity) reactions. The signs may include difficulty breathing or swallowing caused by sudden swelling of the throat, or face or swelling of your hands, feet and ankles
- Severe skin reactions, including blistering, red or purple marks or peeling of the skin. It can also affect the mouth, eyes, nose and genitals (Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme).

Other possible side effects:

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

- Feeling dizzy.
- Headache.
- Feeling weak and tired.
- Low blood pressure. The signs include feeling dizzy or light-headed.
- Swelling and pain in the genitals.

Feeling dizzy, having a headache and feeling weak and tired are usually mild and more likely to happen at the beginning of your treatment.

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

- Infections of the airway (bronchitis), nose and throat (upper respiratory tract). The signs include wheezing, shortness of breath, chest tightness and sore throat
- Problems in passing water.
- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, a fluttering sensation in your heart (palpitations) and being short of breath.
- Increase in weight.
- Increase in cholesterol levels (shown by a blood test).
- Loss of control of blood sugar in people with diabetes.
- Feeling depressed.
- Problems with your sight, sore or dry eyes due to fewer tears being made.
- A slow heart beat.
- Feeling dizzy or light-headed after standing up.
- Fluid retention. The signs include: overall swelling of your body, swelling of parts of your body for example your hands, feet, ankles and legs and an increase in how much blood you have in your body.
- Problems with blood circulation in your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk.
- Breathing problems such as cough or wheezing.
- Feeling sick or being sick.
- Diarrhoea.
- Stomach upset / indigestion.
- Stomach pain.
- Pain, possibly in your hands and feet.
- Problems with your kidneys, including changes to how often you pass urine.

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

- Disturbed sleep.
- Fainting.
- Tingling or numbness of your hands or feet.
- Problems with your skin, including skin rashes which may cover a lot of your body, a lumpy rash (hives), feeling itchy and dry skin patches.
- Hair loss.
- Being unable to get an erection (erectile dysfunction).
- Constipation.

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

- Low numbers of platelets in your blood. The signs include bruising easily and nose bleeds.
- A stuffy nose.

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

- Low numbers of all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs.
- A dry mouth.

- Liver problems which show up in a blood test
- Some women may have difficulty with bladder control when they pass water (urinary incontinence). This normally will get better when treatment is stopped.

Karvedilol Viatris can also cause development of the signs of diabetes in people who have a very mild form of diabetes called “latent diabetes”.

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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Karvedilol 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 pack. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from light.

Do not throw away any medicines 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 Karvedilol Viatris contains

- The active ingredient is carvedilol. Each film-coated tablet contains 3.125 mg, 6.25 mg, 12.5 mg or 25 mg carvedilol.
- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2, ‘Karvedilol Viatris contains lactose’), crospovidone, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), triethyl citrate, macrogol and polydextrose (E1200).

What Karvedilol Viatris looks like and contents of the pack

3.125 mg film-coated tablets: white, oval, and smooth on both sides

6.25 mg film-coated tablets: white, oval, scored on both sides and marked ‘6.25’ on one side

12.5 mg film-coated tablets: white, oval, scored on both sides and marked ‘12.5’ on one side

25 mg film-coated tablets: white, oval, scored on both sides and marked ‘25’ on one side.

Karvedilol Viatris Film-coated Tablets are available in plastic bottles or blister packs containing 10, 14, 28, 30, 50, 56, 98, 100 or 250 (plastic bottle only) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

McDermott Laboratories Ltd t/a Gerard Laboratories
35/36 Baldoye Industrial Estate
Grange Road
Dublin 13

Ireland

Dragenopharm Apotheker Püschl GmbH
Göllstraße 1
84529 Tittmoning
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Mylan Hungary Kft.
H-2900 Komárom
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Hungary

Mylan B.V.
Krijgsman 20
1186 DM Amstelveen,
The Netherlands

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

Sweden - Karvedilol Viatriis 3,125 mg, 6,25 mg, 12,5 mg, 25 mg filmdragerad tablett
Italy - Carvedilolo Mylan Generics 3,125 mg, 6,25 mg, 12,5 mg, 25 mg compresse rivestite con film
Netherlands - Carvedilol Viatriis 3,125 mg, 6,25 mg, 25 mg, filmomhulde tabletten
Portugal - Carvedilol Mylan
Greece - Carvedilol/Generics F.C. Tab 6.25 mg, 12.5 mg, 25 mg
United Kingdom - Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, 25 mg Film-coated Tablets

This leaflet was last revised in 12 April 2024