

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Verquvo® 2.5 mg film-coated tablets

Verquvo® 5 mg film-coated tablets

Verquvo® 10 mg film-coated tablets

Active ingredient

Each tablet contains:

vericiguat 2.5 mg
vericiguat 5 mg
vericiguat 10 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Verquvo is intended to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics, in adults with symptomatic chronic heart failure and ejection fraction (EF, amount of blood pumped with each heartbeat) less than 45%.

Therapeutic group: vasodilators for heart disease, soluble guanylate cyclase stimulator.

Heart failure is a condition in which your heart is weak and cannot pump enough blood to your body. Some common symptoms of heart failure are shortness of breath, tiredness, or swelling caused by a build-up of fluid.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient vericiguat or to any of the other ingredients of this medicine (see section 6 'Additional information')
- you are taking any medicines that contain another **soluble guanylate cyclase stimulator**, such as riociguat used to treat high blood pressure in the lungs

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

Special warnings about using this medicine

Talk to your doctor before taking this medicine if you have:

- **low blood pressure** with symptoms like dizziness or light-headedness
- **severe kidney problems** or are **on dialysis**
- **severe liver problems.**

Children and adolescents

This medicine is not intended for children and adolescents aged under 18 years.

There is no information about the safety and efficacy of using this medicine in children and adolescents under 18 years of age.

Other medicines and Verquvo

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking medicines:

- that belong to the group of soluble guanylate cyclase stimulators (such as riociguat). Do not take Verquvo when taking these medicines. See section 2, 'Do not use this medicine if'.

- used to treat high blood pressure in the lungs, or medicines to achieve or maintain an erection, called PDE5 inhibitors (such as sildenafil, tadalafil, vardenafil). The use of these medicines is not recommended when taking Verquvo.

- used to treat heart disease, including chest pain, called nitrates (such as isosorbide mononitrate).

Pregnancy and breastfeeding

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

Pregnancy

Do not use Verquvo during pregnancy, as it is not known whether it harms the unborn baby. If there is any chance that you could become pregnant, talk to your doctor about reliable forms of contraception.

Breastfeeding

It is not known if Verquvo passes into your breast milk and could harm your baby. Your doctor will decide with you whether breastfeeding or Verquvo therapy should be stopped.

Driving and using machines

If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any machines.

Important information about some of this medicine's ingredients

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

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

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended **starting dose** is **one tablet of 2.5 mg** once daily. Your doctor will adjust the dose depending on how well you tolerate the treatment. Typically, your doctor will increase the dose after about two weeks to one tablet of 5 mg once daily and after another 2 weeks up to the **maximum target dose of 1 tablet of 10 mg** once daily.

If you have **low blood pressure** while taking Verquvo, this can make you feel dizzy and light-headed and your doctor may temporarily reduce your Verquvo dose or temporarily stop your treatment with Verquvo.

Take one tablet at the same time each day with food. If you cannot swallow the tablet, you may crush Verquvo and mix it with water. Take this mixture immediately after preparing it. Do not split the tablet.

Do not exceed the recommended dose.

Adhere to the treatment as recommended by your doctor.

If you have taken a higher dose of Verquvo

Contact your doctor immediately if you take a higher dose of Verquvo and you get any side effects listed in section 4. The most likely effect would be a lowering of your blood pressure, which can make you feel dizzy and light-headed.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Verquvo

Take the missed tablet as soon as you remember, on the same day of the missed dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Verquvo

Do not stop taking this medicine without speaking with your doctor first. If you stop taking Verquvo, your condition may worsen.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Verquvo may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects (may affect more than one in ten users)

- low blood pressure (hypotension)

Common side effects (may affect up to one in ten users)

- low number of red blood cells (anaemia), which can cause pale skin, weakness or breathlessness

- dizziness

- headache

- nausea and vomiting

- indigestion (dyspepsia)

- heartburn (gastro-oesophageal reflux disease).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- This medicine does not require any special storage conditions. Storing at room temperature is recommended.

- Do not throw away the medicine via wastewater or household waste. Ask

the pharmacist how to throw away this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Tablet core:

lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, hypromellose 2910, magnesium stearate, sodium laurilsulfate.

Tablet coating:

hypromellose 2910, titanium dioxide (E 171), talc, ferric oxide red (E 172) (Verquvo 5 mg only), ferric oxide yellow (E 172) (Verquvo 10 mg only).

What the medicine looks like and contents of the pack:

Verquvo 2.5 mg film-coated tablets (tablets) are round, biconvex and white with a diameter of 7 mm, marked with "2.5" on one side and "VC" on the other side.

Verquvo 5 mg film-coated tablets (tablets) are round, biconvex and brown-red with a diameter of 7 mm, marked with "5" on one side and "VC" on the other side.

Verquvo 10 mg film-coated tablets (tablets) are round, biconvex and yellow-orange with a diameter of 9 mm, marked with "10" on one side and "VC" on the other side.

Verquvo is available

- in blisters in cartons of 14, 28 or 98 film-coated tablets

- in perforated unit dose blisters in cartons of 10 × 1 or 100 × 1 film-coated tablets

- in bottles of 100 film-coated tablets

Not all pack sizes may be marketed.

Registration holder's name and address:
Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.

Manufacturer's name and address:

Bayer AG
Kaiser-Wilhelm-Allee 51368 Leverkusen, Germany.

Approved in February 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Verquvo 2.5 mg: 169-16-36992-99

Verquvo 5 mg: 169-17-36993-99

Verquvo 10 mg: 169-18-36994-99