

What is in this leaflet

1. What *Verquvo* is used for
2. How *Verquvo* works
3. Before you use *Verquvo*
4. How to use *Verquvo*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Verquvo*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What *Verquvo* is used for

Verquvo is used to treat adults with long-term heart failure who recently have had an increase in heart failure symptoms. Therefore, you may have gone to hospital and/or received a medicine (diuretic) given in a vein to help you pass more urine than usual.

Heart failure is when 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.

How *Verquvo* works

Verquvo contains the active substance vericiguat, which is a type of heart medicine called soluble guanylate cyclase stimulator. It works by widening the arteries to make it easier for the heart to get more blood and oxygen throughout the body.

Before you use *Verquvo*

- When you must not use it

Do not take *Verquvo* if you are:

- **allergic** to vericiguat or any of the other ingredients of this medicine
- taking any medicine that contains another **soluble guanylate cyclase stimulator**, e.g. riociguat used to treat high blood pressure in lungs.

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

- Before you start to use it

Talk to your doctor or pharmacist before taking *Verquvo* 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

Do not give this medicine to children and adolescents aged under 18 years because it has not been studied yet in this age group.

Pregnancy and breast-feeding

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.

Pregnancy

Verquvo should not be used during pregnancy, as it is not known if it harms the unborn baby. If there is a chance that you could become pregnant, talk to your doctor about reliable forms of contraception.

Breast-feeding

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

- Taking other medicines

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

- belong to the group of soluble guanylate cyclase stimulators (e.g. riociguat). Do not take *Verquvo* when taking these medicines. See “Do not take *Verquvo*”.
- treat high blood pressure in the lungs, or medicines to achieve or maintain an erection, called PDE5 inhibitors (e.g. sildenafil, tadalafil, vardenafil). The use of these medicines is not recommended when taking *Verquvo*.
- treat heart disease including chest pain, called nitrates (e.g. isosorbide mononitrate).

How to use *Verquvo*

- How much to use

- When to use it

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

The recommended **starting dose is 1 tablet of 2.5 mg** once daily. Your doctor will then adjust the dose depending on how well the treatment is tolerated.

Typically, your doctor will increase the dose after about 2 weeks to 1 tablet of 5 mg once daily and after about 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 interrupt 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.

- How long to use it

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

- If you forget to use it

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 use too much (overdose)

Contact your doctor immediately if you take more *Verquvo* than you should and you get any side effects listed below. The most likely effect would be a lowering of your blood pressure which can make you feel dizzy and light-headed.

While you are using it

- Things you must do

Always take this medicine exactly as your doctor has told you.

VERQUVO® (Vericiguat) Film-Coated Tablet 2.5 mg, 5mg, 10mg

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

- Things you must not do

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

- Things to be careful of

Driving and using machines

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

Verquvo contains lactose and sodium

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 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Side Effects

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

The possible side effects are:

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

- low blood pressure (hypotension)

Common (may affect up to 1 in 10 people)

- 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Verquvo

- Storage

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

Store below 30°C.

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

This medicine does not require any special storage conditions.

- Disposal

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.

Product Description

- What it looks like

VERQUVO film coated tablet 2.5mg
Round, biconvex, white film coated tablet with a diameter of 7 mm, marked with “2.5” on one side and “VC” on the other side.

VERQUVO film coated tablet 5mg
Round, biconvex, brown-red film coated tablet with a diameter of 7 mm, marked with “5” on one side and “VC” on the other side.

VERQUVO film coated tablet 10 mg
Round, biconvex, yellow-orange film-coated tablet with a diameter of 9 mm, marked with “10” on one side and “VC” on the other side.

- Ingredients

- Active ingredients
The active substance is vericiguat. Each film coated tablet contains 2.5 mg, 5 mg, or 10 mg of vericiguat.

- Inactive ingredients

Tablet core:

- Cellulose microcrystalline
- Croscarmellose sodium

- Hypromellose
- Lactose monohydrate
- Magnesium stearate
- Sodium lauril sulfate.

Film coat (2.5mg):

- Hypromellose
- Talc
- Titanium dioxide (E171)

Film coat (5mg):

- Hypromellose
- Talc
- Titanium dioxide (E171)
- Ferric oxide red (E172)

Film coat (10mg):

- Hypromellose
- Talc
- Titanium dioxide (E171)
- Ferric oxide yellow (E172)

- MAL number(s):
MALXXXXXXXXXAZ

Manufacturer

Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen
Germany

Product Registration Holder

Bayer Co. (Malaysia) Sdn Bhd
25-03 & 25-04, Level 25, IMAZIUM
No 8, Jalan SS21/37, Damansara Uptown
47400 Petaling Jaya, Selangor, Malaysia

Date of revision

XX/08/2022

Serial Number:

NPRA (R1) 22/007