

Package leaflet: Information for the patient

Verquvo 2.5 mg film-coated tablets

Verquvo 5 mg film-coated tablets

Verquvo 10 mg film-coated tablets

vericiguat

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Verquvo is and what it is used for

Verquvo contains the active substance vericiguat, which is a type of heart medicine called soluble guanylate cyclase stimulator.

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.

2. What you need to know before you take Verquvo

Do not take Verquvo if you are

- allergic to vericiguat or any of the other ingredients of this medicine (listed in section 6),
- 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.

Warnings and precautions

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.

Other medicines and Verquvo

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).

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.

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”.

3. How to take Verquvo

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.

If you take more Verquvo than you should

Contact your doctor immediately if you take more Verquvo than you should 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 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 this medicine, your condition may worsen.

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

4. Possible 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)

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. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):	
Saudi Arabia: The National Pharmacovigilance Centre (NPC). SFDA Call Center: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa	Egypt: Egyptian Pharmaceutical Vigilance Centre Hotline: 15301 Email: pv.followup@edaegypt.gov.eg Website: www.edaegypt.gov.eg
United Arab Emirates (UAE): Pharmacovigilance & Medical Device section Tel: 80011111 / +971 42301000 Email: pv@mohap.gov.ae Website: www.mohap.gov.ae P.O.Box 1853 Dubai	Jordan: Tel: +962-6-5632000 JFDA email : jpc@jfda.jo JFDA website: www.jfda.jo http://primaryreporting.who-umc.org/JO
Kuwait: Drug & Food Control, Ministry of Health Tel.: +965-24811532 Fax: +965-24811507 Email : Adr_reporting@moh.gov.kw Website: http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx	
Other Countries: Please contact the relevant competent authority	

5. How to store Verquvo

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 and on each blister or bottle after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Verquvo contains

- The active substance is vericiguat. Each film-coated tablet contains 2.5 mg, 5 mg or 10 mg vericiguat.
- The other ingredients are:
 - Tablet core:* Microcrystalline cellulose, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, sodium laurilsulfate (see section 2 “Verquvo contains lactose and sodium”).
 - Film-coat:* Hypromellose 2910, talc, titanium dioxide (E 171), iron oxide red (E 172) (Verquvo 5 mg only), iron oxide yellow (E 172) (Verquvo 10 mg only).

What Verquvo 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 (14’s blister), 28 (14’s blister x 2) 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.

Marketing Authorisation Holder

Bayer AG
51368 Leverkusen Germany

Manufacturer

Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen Germany

This leaflet was last revised in July 2021

This is a medicinal product

- A medicine is a product which affects your health and can harm you if taken contrary to directions
- Keep strictly to your doctor’s instructions, the instructions for use and the instructions of the pharmacist who sold you this medicine
- Your doctor and pharmacist are experts on medicine and its benefits and risks
- Do not stop taking this medicine before the end of the prescribed course of treatment
- Do not use this medicine on another occasion without consulting your doctor

Keep medicines out of the reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists