Patient Information Leaflet

SCHEDULING STATUS: S4

VERQALIF 2.5 mg film-coated tablets
VERQALIF 5 mg film-coated tablets
VERQALIF 10 mg film-coated tablets
vericiguat

Contains sugar
VERQALIF 2.5 mg contains 58.14 mg lactose (as monohydrate)
VERQALIF 5 mg contains 55.59 mg lactose (as monohydrate)
VERQALIF 10 mg contains 111.15 mg lactose (as monohydrate)

Read all of this leaflet carefully before you start taking VERQALIF
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- VERQALIF has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VERQALIF is and what it is used for

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

VERQALIF 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 VERQALIF

Do not take VERQALIF:
- if you are **hypersensitive (allergic)** to vericiguat or any of the other ingredients of VERQALIF,
- if you are taking any medicine that contains another **soluble guanylate cyclase stimulator**, e.g. 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking VERQALIF.
- if you have **low blood pressure** with symptoms like dizziness or light-headedness,

- if you have **severe kidney problems** or are **on dialysis**,
- if you have **severe liver problems**.

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

Other medicines and VERQALIF
Always tell your healthcare professional if you are taking, have recently taken or might take any other medicines (including complementary or traditional medicines), in particular medicines that:

- belong to the group of soluble guanylate cyclase stimulators (e.g. riociguat; medicine used for high blood pressure in the lungs). Do not take VERQALIF when taking these medicines. See "Do not take VERQALIF".

- 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 VERQALIF.
- treat heart disease including chest pain, called nitrates (e.g. isosorbide mononitrate).

Pregnancy and breastfeeding and fertility
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 VERQALIF.

Pregnancy
VERQALIF 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.

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

Driving and using machines
If you feel dizzy while taking VERQALIF, do not drive a vehicle, cycle, or use any machines.

VERQALIF contains lactose and sodium
VERQALIF contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VERQALIF.

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

3. How to take VERQALIF

Always take VERQALIF 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 VERQALIF, this can make you feel dizzy and light-headed and your doctor may temporarily reduce your VERQALIF dose or interrupt your treatment with VERQALIF.

Take one tablet at the same time each day with food**.**
If you cannot swallow the tablet, you may crush VERQALIF and mix it with water. Take this mixture immediately.

If you take more VERQALIF than you should
Contact your doctor immediately if you take more VERQALIF 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.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VERQALIF
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 VERQALIF
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

VERQALIF can have side effects.

Not all side effects reported for VERQALIF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VERQALIF, please consult your doctor, pharmacist, or other healthcare professional for advice.

The possible side effects are:

Most frequent (may affect more than 1 in 10 people)
- low blood pressure (hypotension)

Frequent (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)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VERQALIF.

5. How to store VERQALIF

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 after "EXP". The expiry date refers to the last day of that month.

Store VERQALIF at or below 30 °C.

Do not dispose of unused medicines in drains or sewerage system (e.g. toilets). 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 VERQALIF 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 5 cP, lactose monohydrate, magnesium stearate, sodium laurilsulfate (see section 2 "VERQALIF contains lactose and sodium").
  Film-coat: Hypromellose 5 cP, talc, titanium dioxide (E 171), iron oxide red (E 172) (VERQALIF 5 mg only), iron oxide yellow (E 172) (VERQALIF 10 mg only).

What VERQALIF looks like and contents of the pack

VERQALIF 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.

VERQALIF 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.

VERQALIF 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.

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

Holder of Certificate of Registration and Manufacturer

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
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1609

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Verqalif® 10mg – 56/7.1/0814.808