Verquvo® (vericiguat) 2.5, 5, 10 mg film-coated tablets
Prescribing Information

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 2.5 mg / 5 mg / 10 mg vericiguat tablet. **Indication:** Verquvo is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilised after a recent decompensation event requiring IV therapy. **Posology & method of administration:** Vericiguat is administered in conjunction with other heart failure therapies. Before starting vericiguat, optimise volume status & diuretic therapy to stabilise patients after the decompensation event, particularly those with very high NT-proBNP levels. ***Adults:*** *Dose titration:* recommended starting dose is 2.5 mg once daily. Double the dose approx. every 2 weeks to reach target maintenance dose of 10 mg once daily, as tolerated by patient. If patient has tolerability issues, temporary down-titration or discontinuation is recommended. Do not initiate treatment in patients with SBP <100 mmHg. If dose is missed, it should be taken as soon as patient remembers on same day of missed dose. Patients should not take 2 doses on the same day. ***Elderly:*** no dose adjustment ***Renal impairment:*** no dose adjustment in patients with eGFR ≥15 mL/min/1.73 m^2 (without dialysis). Treatment not recommended in patients with eGFR <15 mL/min/1.73 m^2 at treatment initiation or on dialysis. ***Hepatic impairment:*** no dose adjustment for mild/moderate hepatic impairment; treatment not recommended in patients with severe hepatic impairment. ***Paediatrics:*** Safety & efficacy have not been established. No clinical data available. Undesirable effects were observed on growing bone in non-clinical studies. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients; concomitant use of other soluble guanylate cyclase (sGC) stimulators, such as riociguat. **Warnings & precautions (W&P):** Vericiguat may cause symptomatic hypotension. Patients with SBP less than 100 mmHg or symptomatic hypotension at treatment initiation were not studied. The potential for symptomatic hypotension should be considered in patients with hypovolaemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction, history of hypotension, or concomitant treatment with antihypertensives or organic nitrates. If patients experience tolerability issues (symptomatic hypotension or SBP less than 90 mmHg), temporary down-titration or discontinuation of vericiguat is recommended. Concomitant use of vericiguat & PDE5 inhibitors, such as sildenafil, has not been studied in patients with heart failure & is therefore not recommended due to the potential increased risk for symptomatic hypotension. This medicinal product contains lactose. **Interactions:** see Contraindications, W&P section and SmPC for full details. **Pregnancy & breast feeding:** No data on use of vericiguat in pregnant women. Animal studies have shown reproductive toxicity in presence of maternal toxicity. As a precautionary measure, vericiguat should not be used during pregnancy & in women of childbearing potential not using contraception. No information regarding presence of vericiguat in human milk, the effects on breasfed infant or milk production. Vericiguat is present in the milk of lactating rats. Risk to a breastfed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or discontinue/abstain from vericiguat therapy, taking into account the benefit of breast-feeding for the child & the benefit of therapy for the woman. **Effects on ability to drive & use machines:** Vericiguat has minor influence on the ability to drive or use machines. When driving vehicles or operating machines it should be taken into account that dizziness may occur occasionally. **Undesirable effects:** *Very common:* hypotension; *Common:* anaemia, dizziness, headache, nausea, dyspepsia, vomiting, gastro-oesophageal reflux disease. **Overdose:** Overdose of vericiguat may lead to hypotension. If necessary, treat symptoms. Vericiguat is unlikely to be removed by haemodialysis due to high protein binding. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** *2.5mg* - 14 tablets: £45.78. *5mg* – 14 tablets: £45.78. *10mg* - 28 tablets: £91.56. **MA Number(s):** *Great Britain* – PLGB 00010/0748 (2.5 mg), 00010/0749 (5 mg), 00010/0750 (10 mg); *Northern Ireland* - EU/1/21/1561/001–011 (2.5 mg), EU/1/21/1561/012–022 (5 mg), EU/1/21/1561/023–033 (10 mg). **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD, U.K. Telephone: 0118 206 3000.
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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax.: 0118 206 3703, Email: pvuk@bayer.com