swissmedic

Public Summary SwissPAR dated 21 January 2022

Verquvo® (active substance: vericiguat)

First authorisation in Switzerland: 22 September 2021

Medicinal product (film-coated tablets) for the treatment of chronic heart failure

About the medicinal product

The medicinal product Verquvo contains the active substance vericiguat. It is used to treat adults with chronic heart failure[1] who have been sufficiently stabilised following recent decompensation (marked increase in disease-related symptoms including shortness of breath, swelling of the feet and legs due to accumulation of fluid, and fatigue, requiring administration of an intravenous diuretic[2] – usually as an inpatient[3]).

Verquvo is used to reduce the risk of hospital admissions and deaths due to heart failure in these patients. It is used in combination with other therapies for heart failure.

Verquvo was approved as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Verquvo was submitted for assessment to the regulatory authorities in Singapore, Australia and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Further details of the Access joint initiative are published on the Swissmedic website. Access Consortium (swissmedic.ch) .

[1] Heart failure: Heart failure is a condition in which the heart muscle is no longer strong enough to pump sufficient blood throughout the body.

[2] Diuretic: A diuretic is a medicinal product that promotes the excretion of urine.

[3] Inpatient: An inpatient is someone who needs to stay in a hospital or nursing home for the treatment.

Mode of action

Verquvo is a soluble guanylate cyclase stimulator (sGC stimulator). sGC is an enzyme which is present in vascular and cardiac muscle, where it generates an important intracellular messenger substance: cyclic guanosine monophosphate (cGMP). cGMP is involved in regulating vascular tone and the ability of cardiac muscle to contract. Patients with heart failure have reduced sGC activity. Verquvo can correct this deficit, thereby improving cardiovascular[4] function in the treated patients.

Use

Verquvo is a prescription-only medicine and is available in three different doses (2.5 mg, 5 mg and 10 mg of the active substance vericiguat).

The standard dose is one 10 mg film-coated tablet per day; as rule, treatment begins with one 2.5 mg film-coated tablet per day.

The film-coated tablet should be taken at the same time every day with food.

Efficacy

The efficacy of Verquvo was mainly investigated in the VICTORIA study, which involved more than 5,000 adult patients with chronic heart failure and reduced cardiac output.

The patients received either Verquvo or a placebo (dummy drug) alongside a conventional therapy for heart failure. The occurrence of cardiovascular deaths or hospitalisations due to worsening heart failure was used for primary analysis. Treatment with Verquvo resulted in a statistically significant reduction (composite primary endpoint) compared to placebo treatment.

Precautions, undesirable effects & risks

Verquvo must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effect of Verquvo is low blood pressure (hypotension).

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Approx. 2% of all adults worldwide suffer from chronic heart failure. Between 6 and 10% of all people over 65 are affected.

The VICTORIA study showed a statistically significant reduction in the number of hospitalisations or deaths following treatment with Verquvo.

4 Cardiovascular: cardiovascular means conserning the heart and the vessels.

Taking all the risks (hypotension and hypo precautions into account, and based on the available data, the benefits of Verquvo outweigh the risks. Swissmedic has therefore authorised the medicinal product Verquvo with the active substance vericiguat for the treatment of adults with chronic heart failure whose disease-related symptoms have recently increased.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Verquvo®

Information for patients (package leaflet):
Information for patients Verquvo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.