LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pahrilan
(riociguat)

SE/H/2695/001-005/DC

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Summary Public Assessment Report

Pahrilan
riociguat

Film-coated tablet, 0,5 mg, 1 mg, 1,5 mg, 2 mg, 2,5 mg

This is a summary of the public assessment report (PAR) for Pahrilan. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pahrilan and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Adempas.

The product is used in the treatment of adults and children from 6 years of age with certain types of pulmonary hypertension:

- **Chronic thromboembolic pulmonary hypertension (CTEPH).**
  The product is used to treat adult patients with CTEPH. In patients with CTEPH, the blood vessels of the lung are blocked or narrowed by blood clots. The medicine can be used in patients with CTEPH who cannot be operated on, or in patients in whom pulmonary hypertension remains or returns after surgery.
- **Pulmonary arterial hypertension (PAH).**
  The product is used to treat adults and children aged 6 years or older with pulmonary arterial hypertension. In these patients, the walls of the blood vessels of the lungs are thickened and the vessels become narrowed. In patients with PAH, the product is taken together with certain other medicines (so-called endothelin receptor antagonists). In adults, the medicine can also be taken on its own (monotherapy).

How does Pahrilan work?
In patients with pulmonary hypertension, the blood vessels that carry blood from the heart to the lungs become narrowed, making it harder for the heart to pump blood to the lungs, and leading to high blood pressure in the vessels. Because the heart must work harder than normal, people with pulmonary hypertension feel tired, dizzy and short of breath. The product widens the blood vessels that lead from the heart to the lungs, reducing symptoms of the disease and better allowing patients to carry out physical activity better.

How is Pahrilan used?
The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Pahrilan have been shown in studies?
Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Adempas. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Pahrilan?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is Pahrilan approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Adempas, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pahrilan?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Pahrilan
The full PAR for Pahrilan can be found on the following website: MRI - Home. For more information about treatment with Pahrilan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.