Part VI: Summary of the risk management plan

Summary of risk management plan for Pahrilan 0.5 mg, 1 mg, 1.5 mg, 2 mg & 2.5 mg filmdragerade tabletter (riociguat)

This is a summary of the risk management plan (RMP) for Pahrilan 0.5 mg, 1 mg, 1.5mg, 2 mg & 2.5 mg filmdragerade tabletter [Pahrilan]. The RMP details important risks of Pahrilan , how these risks can be minimised, and how more information will be obtained about Pahrilan's risks and uncertainties (missing information).

Pahrilan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pahrilan should be used.

Important new concerns or changes to the current ones will be included in updates of Pahrilan's RMP.

I. The medicine and what it is used for

Pahrilan is authorised for:

- Chronic thromboembolic pulmonary hypertension (CTEPH)

  Pahrilan is indicated for the treatment of adult patients with WHO Functional Class (FC) II to III with

  - inoperable CTEPH,
  - persistent or recurrent CTEPH after surgical treatment,

  to improve exercise capacity.

- Pulmonary arterial hypertension (PAH)

  - *Adults:* Pahrilan, as monotherapy or in combination with endothelin receptor antagonists, is indicated for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III to improve exercise capacity.
  - *Paediatrics:* Pahrilan is indicated for the treatment of PAH in paediatric patients aged 6 to less than 18 years with WHO Functional Class (FC) II to III in combination with endothelin receptor antagonists.

Pahrilan contains riociguat as the active substance and it is given orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pahrilan , together with measures to minimise such risks and the proposed studies for learning more about Pahrilan’s risks, are outlined below.

Routine risk minimization measures for medicinal products can be:

• Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.

• Important advice on the medicine's packaging.

• The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.

• The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Pahrilan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Pahrilan . Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Bone safety in patients <18 years old
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Pahrilan.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Pahrilan.