Part VI: Summary of the risk management plan

Summary of risk management plan for Macitentan STADA 10 mg film-coated tablets (Macitentan)

This is a summary of the risk management plan (RMP) for Macitentan STADA. The RMP details important risks of Macitentan STADA, how these risks can be minimised, and how more information will be obtained about for Macitentan STADA risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Macitentan STADA is authorised, for adults, as monotherapy or in combination, for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III. Macitentan STADA is authorised, for paediatric population, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged less than 18 years and bodyweight ▪ 40 kg with WHO Functional Class (FC) II to III (see SmPC for the full indication). It contains macitentan 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 Macitentan STADA, together with measures to minimise such risks and the proposed studies for learning more about Macitentan STADA's risks, are outlined below.

Measures to minimise the risks identified 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 the case of Macitentan STADA, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Macitentan STADA 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 Macitentan STADA. 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	• Hepatotoxicity • Teratogenicity
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Important Identified risk: Hepatotoxicity	
Risk minimisation measures	**Routine risk minimisation measures:** Covered under the following sections of SmPC: 4.3, 4.4 and 4.8. Advice to patients provided in PL. Instructions for liver function monitoring and actions to be taken in case of elevated hepatic enzymes are provided in SmPC section 4.4. **Other routine risk minimisation measures:** Prescription only medicine. **Additional risk minimisation measure(s):**

Important Identified risk: Hepatotoxicity	
	Patient card.

Important Identified risk: Teratogenicity	
Risk minimisation measures	**Routine risk minimisation measures:** Covered under the following section of SmPC: 4.3, 4.4 and 4.6. Advice to patients provided in PL. Instructions for the use of Macitetntan in women of childbearing potential and recommendation for monthly pregnancy tests during treatment are provided in SmPC section 4.4. **Other routine risk minimisation measures:** Prescription only medicine. **Additional risk minimisation measure(s):** Patient card.

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 Macitentan STADA.

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

There are no studies required for Macitentan STADA