

Part VI: Summary of the risk management plan

Summary of risk management plan for Macitentan Viatris (macitentan)

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

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

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

I. The medicine and what it is used for

Macitentan Viatris is authorised for the long-term treatment of pulmonary arterial hypertension (PAH) in adult and paediatric patients of WHO Functional Class (FC) II to III, as monotherapy or in combination. (see SmPC for the full indication).

It contains Macitentan as the active substance and it is given by oral route.

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

Important risks of Macitentan Viatris, together with measures to minimise such risks and the proposed studies for learning more about Macitentan Viatris 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 Viatris, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

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 Macitentan Viatris 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 Viatriis. 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);

Table 5: Part VI.1- Summary of safety concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> • Hepatotoxicity • Teratogenicity
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • None

II.B Summary of important risks

Table 6 Part VI.2- Hepatotoxicity.

Risk Measures	Minimisation
	<p>Routine risk minimisation measures</p> <p>SmPC section 4.3 ‘Contraindication’ and PL section 2, ‘What you need to know before you take Macitentan Viatriis</p> <p>SmPC section 4.4 ‘Special Warnings and Precautions for Use’ and PL section2, ‘What you need to know before you take Macitentan Viatriis</p> <p>SmPC section 4.8 ‘Undesirable Effects’ and PL section 4 ‘Possible side effects’</p> <p>Instructions for liver function monitoring and actions to be taken in case of elevated hepatic enzymes are provided in SmPC Section 4.4</p> <p>Medicine’s legal status: Medicinal product subject to restricted medical prescription.</p> <p>Additional risk minimisation measures:</p> <p>Risk minimization tools (patient card)</p>

Table 7 Part VI.3- Teratogenicity.

Risk Measures	Minimisation
	<p>Routine risk minimisation measures</p> <p>SmPC section 4.3 ‘Contraindication’ and PL section 2 ‘What you need to know before you take Macitentan Viatriis</p> <p>SmPC section 4.4 ‘Special Warnings and Precautions for Use’ and PL section 2 ‘What you need to know before you take Macitentan Viatriis</p> <p>SmPC section 4.6 ‘Fertility, pregnancy, and lactation’ and PL section 2 ‘What you need to know before you take Macitentan Viatriis</p>

	<p>Instructions for the use of Macitentan Viatris in women of childbearing potential and recommendation for monthly pregnancy tests during treatment are provided in SmPC section 4.4</p> <p>Medicine's legal status: Medicinal product subject to restricted medical prescription.</p> <p>Additional risk minimisation measures:</p> <p>Risk minimization tools (patient card)</p>
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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 Viatris.

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

There are no studies required for Macitentan Viatris.