

Part VI: Summary of the risk management plan

Summary of risk management plan for Tadalafil AOP (Tadalafil)

This is a summary of the risk management plan (RMP) for Tadalafil AOP. The RMP details important risks of Tadalafil AOP, and how more information will be obtained about Tadalafil AOP's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Tadalafil AOP is authorised for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity. (see SmPC for the full indication). It contains Tadalafil as the active substance and it is given orally in the form of tablets.

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

Important risks of Tadalafil AOP, together with measures to minimise such risks and the proposed studies for learning more about Tadalafil AOP'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 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*.

If important information that may affect the safe use of Tadalafil AOP is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tadalafil AOP 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 Tadalafil AOP. 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	Priapism
	Hypotension/Increased Hypotensive Effect
Important potential risks	Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION)
	Sudden Hearing Loss

List of important risks and missing information	
	Increased uterine bleeding
Missing information	Characterization of adverse events in elderly patients (>65 years)

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 Tadalafil AOP.

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

There are no studies required for Tadalafil AOP.