Part VI: Summary of the risk management plan

Summary of risk management plan for TADALAFIL ALFRAPHARMA (as tadalafil)

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

Summary of product characteristics (SmPC) of TADALAFIL ALFRAPHARMA and its package leaflet give essential information to healthcare professionals and patients on how TADALAFIL ALFRAPHARMA should be used.

Important new concerns or changes to the current ones will be included in updates of RMP of TADALAFIL ALFRAPHARMA.

I. The medicine and what it is used for

TADALAFIL ALFRAPHARMA is proposed to be indicated for:

- Treatment of erectile dysfunction in adult males.
- *5 mg only*: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

TADALAFIL ALFRAPHARMA contains tadalafil as active substance and it is given by oral route of administration.

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

Important risks of TADALAFIL ALFRAPHARMA together with measures to minimise such risks and the proposed studies for learning more about risks of TADALAFIL ALFRAPHARMA, 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, including PSUR assessment - 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 ALFRAPHARMA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of TADALAFIL ALFRAPHARMA 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 ALFRAPHARMA. 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 part VI-IIa: List of important risks and missing information

Summary of safety concerns	
Important identified risks	• Priapism • Hypotension/increased hypotensive effect
Important potential risks	• Non-arteritic anterior ischaemic optic neuropathy (NAION) • Sudden hearing loss
Missing information	• Characterisation 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 ALFRAPHARMA.

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

There are no studies required for TADALAFIL ALFRAPHARMA.