Part VI: Summary of the risk management plan

Summary of risk management plan for Tadalafil STADA Nordic 5 mg, 10 mg and 20 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Tadalafil STADA Nordic 5 mg, 10 mg and 20 mg film-coated tablets. The RMP details important risks of Tadalafil STADA Nordic, how these risks can be minimised, and how more information will be obtained about Tadalafil STADA Nordic's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Tadalafil STADA Nordic is authorised for the treatment of erectile dysfunction in adult males (Tadalafil STADA Nordic 2.5 mg, 5 mg, 10 mg, 20 mg film-coated tablets) and for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males (Tadalafil STADA Nordic 5 mg film-coated tablets). (see SmPC for the full indication). It contains tadalafil 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 Tadalafil STADA Nordic, together with measures to minimise such risks and the proposed studies for learning more about Tadalafil STADA Nordic'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.

If important information that may affect the safe use of Tadalafil STADA Nordic is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Tadalafil STADA Nordic 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 STADA Nordic. 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	• Nonarteritic Anterior Ischemic 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 STADA Nordic.

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

There are no studies required for Tadalafil STADA Nordic.