

# EU Risk Management Plan for <Product name> (Tadalafil)

## Part VI: Summary of the risk management plan

### Summary of risk management plan for <Product name> (Tadalafil)

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

<Invented name>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <invented name> should be used.

#### I. The medicine and what it is used for

<Invented name> is authorised for the treatment of erectile dysfunction in adult males (<Product name> 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 (<Product name> 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 <invented name>, together with measures to minimise such risks and the proposed studies for learning more about <invented name>'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 <invented name> is not yet available, it is listed under 'missing information' below.

## **II.A List of important risks and missing information**

Important risks of <invented name> 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 <invented name>. 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);

| <b>List of important risks and missing information</b> |   |
|--|---|
| Important identified risks                             | <ul style="list-style-type: none"><li>• Priapism</li><li>• Hypotension/increased hypotensive effect</li></ul>                           |
| Important potential risks                              | <ul style="list-style-type: none"><li>• Nonarteritic Anterior Ischemic Optic Neuropathy (NAION)</li><li>• Sudden hearing loss</li></ul> |
| Missing information                                    | <ul style="list-style-type: none"><li>• Characterisation of adverse events in elderly patients (≥65 years)</li></ul>                    |

## **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 <invented name>.

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

There are no studies required for <invented name>.