Summary of risk management plan for TADALAFIL ORION (Tadalafil) Orion Corporation

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Summary of risk management plan for Tadalafil Orion 2.5mg, 5 mg, 10 mg & 20 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Tadalafil Orion 2.5mg, 5 mg, 10 mg & 20 mg film-coated tablets (hereinafter referred to as Tadalafil).

The RMP details important risks of Tadalafil, how these risks can be minimised, and how more information will be obtained about Tadalafil's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

For 5 mg film-coated tablets:
Tadalafil is indicated for:
- Treatment of erectile dysfunction in adult males.
In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.
- Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.
- Tadalafil Orion is not indicated for use by women.

For 2.5mg, 10 mg & 20 mg film-coated tablets:
Tadalafil is indicated for:
- Treatment of erectile dysfunction in adult males.
In order for tadalafil to be effective, sexual stimulation is required.
- Tadalafil Orion is not indicated for use by women.
(See SmPC for the full indication). It contains Tadalafil as the active substance and is given orally.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Tadalafil together with measures to minimise such risks and the proposed studies for learning more about Tadalafil'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 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 the 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 Tadalafil 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. 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	None
Important potential risks	None
Missing information	None

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.

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

There are no studies required for Tadalafil.