Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Cialis (tadalafil)

This is a summary of the RMP for Cialis®. The RMP details important risks of Cialis, how these risks can be minimised, and how more information will be obtained about Cialis's risks and uncertainties (missing information).

Cialis's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Cialis should be used.

This summary of the RMP for Cialis should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

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

I - The Medicine and What It is Used for

Cialis is authorised for erectile dysfunction (ED), benign prostatic hyperplasia (BPH), ED and BPH (ED/BPH) (see SmPC for the full indication). It contains tadalafil as the active substance and it is given by oral administration.

Further information about the evaluation of Cialis's benefits can be found in Cialis's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/cialis.

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

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*.

Summary of Risk Management Plan for Adcirca (tadalafil)

This is a summary of the RMP for Adcirca®. The RMP details important risks of Adcirca, how these risks can be minimised, and how more information will be obtained about Adcirca's risks and uncertainties (missing information).

Adcirca's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Adcirca should be used.

This summary of the RMP for Adcirca should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

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

I - The Medicine and What It is Used for

Adcirca is authorised for PAH (see SmPC for the full indication). It contains tadalafil as the active substance and it is given by oral administration.

Further information about the evaluation of Adcirca's benefits can be found in Adcirca's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/adcirca

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

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*.

Summary of Risk Management Plan for Tadalafil Lilly (tadalafil)

This is a summary of the RMP for Tadalafil Lilly®. The RMP details important risks of Tadalafil Lilly, how these risks can be minimised, and how more information will be obtained about Tadalafil Lilly's risks and uncertainties (missing information).

Tadalafil Lilly's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Cialis should be used.

This summary of the RMP for Cialis should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

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

I - The Medicine and What It is Used for

Tadalafil Lilly is authorised for erectile dysfunction (ED) (see SmPC for the full indication). It contains tadalafil as the active substance and it is given by oral administration.

Further information about the evaluation of Tadalafil Lilly's benefits can be found in tadalafil Lilly's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/tadalafil-lilly.

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

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*.

II.A List of Important Risks and Missing Information

Important risks of Cialis/Adcirca/Tadalafil Lilly 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 Cialis/Adcirca/Tadalafil Lilly. 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 risk	None
Important potential risk	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 that are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Cialis, Adcirca, or Tadalafil Lilly.

II.C.2 Other Studies in Post-Authorisation Development Plan

Not applicable.