Summary of Risk Management Plan for Levitra (vardenafil)

This is a summary of the risk management plan (RMP) for Levitra.

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

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

Important new concerns will be included in updates of Levitra's RMP.

I. The Medicine and what it is used for

Levitra is authorised for treatment of erectile dysfunction in adult men. Erectile dysfunction is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

- Each tablet of 5 mg film-coated tablets contains 5 mg of vardenafil (as hydrochloride).
- Each tablet of 10 mg film-coated tablets contains 10 mg of vardenafil (as hydrochloride).
- Each tablet of 20 mg film-coated tablets contains 20 mg of vardenafil (as hydrochloride).
- Each tablet of 10 mg orodispersible tablets contains 10 mg of vardenafil (as hydrochloride).

Further information about the evaluation of Levitra's benefits can be found in Levitra's EPAR, available on the EMA website.

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

The risks of Levitra, together with measures to minimise such 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PBRER/PSUR, 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 Levitra is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Vardenafil has been marketed for more than 15 years; all the risks mentioned as per previous RMPs are fully characterised and appropriately managed through routine risk minimisations and there are no outstanding ongoing additional pharmacovigilance activities; therefore, all the important identified risks have been be removed from the safety specifications. Regarding the important potential risks, it is very unlikely that any pharmacovigilance activity can further characterise these risks; thus, it was considered that all the important potential risks have been deleted.

The summary of safety concerns is presented as follows:

Table 1: Summary of safety concerns

Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of Important Risks

Not applicable, as there were no important identified risk, potential risk, and missing information.

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 Levitra.

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

There are no studies required for Levitra.