
Part VI: Summary of the risk management plan

Summary of risk management plan for SILANDYL (Sildenafil citrate)

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

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

SILANDYL's Summary of product characteristics (SmPC) and package leaflet give essential information to healthcare professionals and patients on how it should be appropriately used to take advantage of its therapeutic benefits limiting unwanted side effects.

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

I. The medicine and what it is used for

SILANDYL is indicated for adult male patient with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for SILANDYL to be effective, sexual stimulation is required (see SmPC for details). It contains sildenafil citrate as the active substance, and it is taken orally, by the supralingual route - the orodispersible film should be placed in the mouth, on the tongue, and allowed to dissolve before swallowing.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of SILANDYL, together with measures to minimise such risks and the proposed studies for learning more about their shared 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 PSUR assessment 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 SILANDYL is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of SILANDYL 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 SILANDYL. 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).

For SILANDYL, no important risks or missing information have been identified:

Summary of safety concerns	
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 SILANDYL.

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

There are no other studies required for SILANDYL.