

PART VI: Summary of the risk management plan

Summary of risk management plan for Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets (Solifenacin Succionate)

This is a summary of the risk management plan (RMP) for Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets. The RMP details important risks of Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets and how more information will be obtained about Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets risks and uncertainties (missing information).

Solifenacin Medical Valley 5 mg and 10 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets is indicated in adults for symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.

It contains Solifenacin Succionate as the active substance and it is given by the oral route.

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

Important risks of Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets, 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 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 Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets are risks that need special risk minimisation 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 Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets. 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	• Hypersensitivity reactions, including anaphylactic reaction and angioedema • Urinary retention • Cardiac rhythm disorders • Glaucoma • Ileus
Important Potential Risks	• None
Missing Information	• Use of solifenacin in infants and children either exposed to solifenacin directly or exposed via breast-feeding • Use during pregnancy

II.B Summary of important risks

The safety information in the 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 Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets.

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

There are no studies required for Solifenacin Medical Valley 5 mg and 10 mg film-coated tablets.

