PART VI: Summary of the risk management plan
The content of this part is the same for both strengths (5 mg and 10 mg) of Solifenacin film-coated tablets.

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

I. The medicine and what it is used for
Solifenacin 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 as the active substance and it is given orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks
Important risks of Solifenacin 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;

• 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.
If important information that may affect the safe use of Solifenacin 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 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 administered. 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 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	• Anaphylactic reactions • Urinary retention • QT prolongation/ Torsade de Pointes • Glaucoma • Ileus
Important Potential Risks	• Failure to thrive after using during lactation
Missing Information	• Safety in paediatric population • Safety in pregnancy

II.B Summary of important risks

The safety information in the proposed SmPC is aligned to that of 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 5 mg and 10 mg film-coated tablets.

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

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