Part VI: Summary of the risk management plan

Summary of risk management plan for <Product name> (Solifenacin)

This is a summary of the risk management plan (RMP) for <Product name>. The RMP details important risks of <Product name>, how these risks can be minimised, and how more information will be obtained about <Product name>'s risks and uncertainties (missing information).

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

I. The medicine and what it is used for

<Product name> is authorised in adults for symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome (see SmPC for the full indication). 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 <Product name>, together with measures to minimise such risks and the proposed studies for learning more about <Product name>'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;
- 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.

If important information that may affect the safe use of <Product name> is not yet available, it is listed under 'missing information' below.

1.1 List of important risks and missing information

Important risks of <Product name> 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 <Product name>. 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	• QTc prolongation/Torsades de Pointes • Urinary retention • Hypersensitivity reactions, including anaphylactic reaction and angioedema • Glaucoma • Ileus
Important potential risks	• None
Missing information	• Use of solifenacin in children under the age of six months, either exposed to solifenacin directly or exposed via breast-feeding • Use in pregnancy

1.2 Summary of important risks

QTc prolongation/Torsades de Pointes **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.4, 4,8 and 4.9* - Prescription only medicine Additional risk minimisation measures: - *N/A*

Urinary retention **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.4, 4,8 and 4.9* - Prescription only medicine Additional risk minimisation measures: *N/A*

Hypersensitivity reactions, including anaphylactic reaction and angioedema **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.4, and 4.8*

Hypersensitivity reactions, including anaphylactic reaction and angioedema **Important identified risk**	
	- Prescription only medicine <u>Additional risk minimisation measures:</u> *N/A*

Glaucoma **Important identified risk**	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> *SmPC sections 4.3 and 4.8* - Prescription only medicine <u>Additional risk minimisation measures:</u> *N/A*

Ileus **Important identified risk**	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> *SmPC section 4.8* - Prescription only medicine <u>Additional risk minimisation measures:</u> *N/A*

1.3 Summary of missing information

Use of solifenacin in children under the age of six months, either exposed to solifenacin directly or exposed via breast-feeding **Missing information**	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> *SmPC sections 4.2 and 5.2* - Prescription only medicine <u>Additional risk minimisation measures:</u> *N/A*

Use in pregnancy Missing information	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.6* - Prescription only medicine Additional risk minimisation measures: *N/A*

1.4 Post-authorisation development plan

1.4.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of <Product name>.

1.4.2 Other studies in post-authorisation development plan

There are no studies required for <Product name>.