Part VI: Summary of risk management plan for Fesoterodine 4 mg & 8 mg prolonged-release tablets

This is a summary of the risk management plan (RMP)Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets. The RMP details important risks of Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets, how these risks can be minimised, and how more information will be obtained about Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tabletsrisks and uncertainties (missing information).

Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tabletsshould be used.

I. The medicine and what it is used for

Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets is authorised for adults, for treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur with overactive bladder syndrome (see SmPC for the full indication). It contains fesoterodine as the active substance, and it is given by oral route.

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

Important risks of Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tabletstogether 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 Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tabletsis not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tabletsare risks that need special risk management activities to further investigate or minimise the risks, 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 Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release 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	- Urinary retention - Angioedema

Important potential risks	- QT prolongation - Liver enzyme elevations - Cognitive function
Missing information	- Elderly male patients - Paediatric patients - Pregnant or nursing women

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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets.

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

There are no studies required for Fesoterodine Medical Valley 4 mg & 8 mg prolonged release tablets, Fesoterodine Pinewood 4 mg & 8 mg prolonged release tablets, Fesoterodine Rowa 4 mg & 8 mg prolonged-release tablets, Fesoterodine Liconsa 4 mg & 8 mg prolonged release tablets.