Part VI: Summary of the risk management plan

Summary of risk management plan for Tamsulosin+Solifenacin

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

Tamsulosin+Solifenacin's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tamsulosin+Solifenacin should be used.

I. The medicine and what it is used for

Tamsulosin+Solifenacin is authorised for treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.

It contains tamsulosin hydrochloride and solifenacin succinate as the active substances and it is given by oral route of administration.

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

Important risks of Tamsulosin+Solifenacin, together with measures to minimise such risks and the proposed studies for learning more about Tamsulosin+Solifenacin'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.

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*.

II.A List of important risks and missing information

Important risks of Tamsulosin+Solifenacin 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 Tamsulosin+Solifenacin. 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	Glaucoma
	Hypersensitivity reactions, including anaphylactic reaction and angioedema

List of important risks and missing information	
	Intraoperative Floppy Iris Syndrome
	Ileus
	Orthostatic hypotension
	QT prolongation/ Torsade de Pointes
	Urinary retention
Important potential risks	Concomitant administration with strong CYP3A4 inhibitors
Missing information	None

II.B Summary of important risks

The safety information in the proposed product information is aligned to that of the reference medicinal product Vesomni® (1).

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 the Applicant's Tamsulosin+Solifenacin.

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

There are no studies required for the Applicant's Tamsulosin+Solifenacin.