Part VI: Summary of risk management plan for Tamsulosin 0.4 mg modified-release capsules, hard

This is a summary of the risk management plan (RMP) for Tamsulosin 0.4 mg modified-release capsules, hard. The RMP details important risks of Tamsulosin 0.4 mg modified-release capsules, hard, how these risks can be minimised, and how more information will be obtained about Tamsulosin 0.4 mg modified-release capsules, hard risks and uncertainties (missing information).

Tamsulosin 0.4 mg modified-release capsules, hard summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tamsulosin 0.4 mg modified-release capsules, hard should be used.

Important new concerns or changes to the current ones will be included in updates of Tamsulosin 0.4 mg modified-release capsules, hard 'RMP.

I. The medicine and what it is used for

Tamsulosin 0.4 mg modified-release capsules, hard is used to lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).
It contains tamsulosin 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 Tamsulosin 0.4 mg modified-release capsules, hard 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.

II. A List of important risks and missing information

Important risks of Tamsulosin 0.4 mg modified-release capsules, hard are risks that need special risk management activities to further investigate or minimise the risks, 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 Tamsulosin 0.4 mg modified-release capsules, hard. 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). If important information that may affect the use of Tamsulosin 0.4 mg modified-release capsulesis not yet available, it is listed under 'missing information' below.