PART VI- Summary of the risk management plan

Summary of risk management plan for DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules (product name in RMS).

This is a summary of the risk management plan (RMP) for DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules. The RMP details important risks of DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules, how these risks can be minimised, and how more information will be obtained about DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules' risks and uncertainties (missing information).

DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules should be used.

I. The medicine and what it is used for

DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules is indicated for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH) and for reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH (see SmPC for the full indication). It contains dutasteride and tamsulosin as active substances 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 DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules, 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.

If important information that may affect the safe use of DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules are risks that need special risk management 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 DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules. 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

Summary of safety concerns	
Important identified risks	•Sexual adverse events (altered [decreased] libido, impotence, ejaculation disorder) •Cardiac failure •SJS, dermatitis exfoliative and erythema multiforme •Depressed mood •Priapism •Breast disorders (enlargement and tenderness)
Important potential risks	•Cardiovascular events (other than cardiac failure) including atrial fibrillation, tachycardia, arrhythmias and dyspnoea •Male breast cancer •High-grade prostate cancer •Interference with formation of external male genitalia in the foetus
Important missing information	•Use in patients with severe hepatic impairment •Use in men with unstable medical conditions such as recent myocardial infarction, coronary bypass surgery, unstable angina, cardiac arrhythmias, clinically evident congestive heart failure, or cerebrovascular accident, cancer or uncontrolled diabetes or peptic ulcer disease

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product Combodart.

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 DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules.

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

There are no studies required for DUTASTERIDE TAMSULOSIN 0.5 mg / 0.4 mg hard capsules.