Part VI: Summary of the risk management plan

Summary of risk management plan for Dutasterid Alkaloid (dutasteride)

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

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

Important new concerns or changes to the current ones will be included in updates of Dutasterid Alkaloid's RMP.

I. The medicine and what it is used for

Dutasterid Alkaloid is authorised for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH) and 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 as the active substance and it is given by oral administration.

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

Important risks of Dutasterid Alkaloid, together with measures to minimise such risks and the proposed studies for learning more about Dutasterid Alkaloid’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 Dutasterid Alkaloid is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dutasterid Alkaloid 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 Dutasterid Alkaloid. 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 *(from Part II: Module SVIII)*	
Important identified risks	• Cardiac failure • Male breast cancer
Important potential risks	• Cardiovascular events other than cardiac failure (myocardial infarction or stroke) • High-grade prostate cancer • Interference with formation of external male genitalia in the foetus
Missing information	• 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, and amended in accordance with the comments received by RMS/CMS during the procedure.

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 Dutasterid Alkaloid.

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

There are no studies required for Dutasterid Alkaloid.