Summary of the risk management plan for Dutasteride 0.5 mg Soft Gelatin Capsule

This is a summary of the risk management plan (RMP) for Dutasteride 0.5 mg Soft Gelatin Capsule. The product name (s) in the RMS are: - Dutasterid Liconsa 0,5 mg, bløde kapsler, Deridust, Dutasteride ”Chemo Ibérica”, Dutasterid "Universal Farma", Dutasteride Medical Valley and Tasdurit 0.5 mg, bløde kapsler and Dutasteride 0.5 mg soft capsules

The RMP details important risks of Dutasteride 0.5 mg Soft Gelatin Capsule, how these risks can be minimised, and how more information will be obtained about Dutasteride 0.5 mg Soft Gelatin Capsule risks and uncertainties (missing information).

Dutasteride 0.5 mg Soft Gelatin Capsule summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dutasteride 0.5 mg Soft Gelatin Capsule should be used.

Important new concerns or changes to the current ones will be included in updates of Dutasteride 0.5 mg Soft Gelatin Capsule 's RMP.

I. The medicine and what it is used for

Dutasteride 0.5 mg Soft Gelatin Capsule 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 route.

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

Important risks of Dutasteride 0.5 mg Soft Gelatin Capsule 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 Dutasteride 0.5 mg Soft Gelatin Capsule 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 0.5 mg Soft Gelatin Capsule. 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).

Table 01. Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	- None
Important potential risks	- None
Missing information	- None

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 authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Dutasteride 0.5 mg Soft Gelatin Capsule.

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

There are no studies required for Dutasteride 0.5 mg Soft Gelatin Capsule.