This is a summary of the risk management plan (RMP) for Dutasterid “Laboratorios Liconsa” 0.5 mg soft gelatin capsule.

The RMP details important risks of Dutasterid “Laboratorios Liconsa” 0.5 mg soft gelatin capsule, how these risks can be minimised, and how more information will be obtained about Dutasterid “Laboratorios Liconsa” 0.5 mg soft gelatin capsule risks and uncertainties (missing information).
Dutasterid “Laboratorios Liconsa” 0.5 mg soft gelatin capsule 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dutasteride should be used.

I. The medicine and what it is used for

Dutasteride is indicated for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH). Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

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

Important risks of Dutasteride, 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dutasteride 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. 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	•Reproductive systems - Sexual adverse events of altered (decreased) libido, impotence, ejaculation disorder that may persists after drug discontinuation - Breast disorder (enlargement and tenderness) •Allergic reaction, including rash, pruritus, urticarial, localised oedema and angioedema •Cardiac failure •Depressed mood
Important potential risks	•Cardiovascular events other than cardiac failure •Male breast cancer •High-grade prostate cancer •Interference with formation of external male genitalia of the foetus
Important missing information	• Safety of dutasteride therapy in: - Men with severe hepatic impairment •Safety of dutasteride therapy 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.

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.

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

There are no studies required for Dutasteride.