Part VI: Summary of the risk management plan

Summary of risk management plan for Finasteride.

This is a summary of the risk management plan (RMP) for Finasteride. The RMP details important risks of Finasteride, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about Finasteride risks and uncertainties (missing information).

Finasteride Summary of product characteristics gives essential information to healthcare professionals and patients on how Finasteride should be used.

I. The medicine and what it is used for

Finasteride 1 mg is authorised for early stages of androgenetic alopecia and finasteride 5 mg is authorised for treatment and control of benign prostatic hyperplasia (see SmPC for the full indication). It contains finasteride 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 Finasteride, together with measures to minimise such risks and learning more about Finasteride 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 leaflets and SmPCs 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.

II.A List of important risks and missing information

Important risks of Finasteride 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 Finasteride. 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.

Important identified risks	Off label use in women and adolescents
	Exposure during pregnancy
Important potential risks	Persistence of Sexual Dysfunction (decreased libido, erectile dysfunction and ejaculation disorders) following discontinuation
	Male infertility
	Depressive disorder
	Male Breast Cancer
Missing information	None

II.B Summary of important risks

The safety information in the proposed Summary of product characteristics, Labelling and Package information leaflet is aligned to the reference medicinal product.

II.C Post-authorisation development plan

No post authorisation study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or which are a specific obligation of Finasteride.

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

There are no studies required for Finasteride.