VI.2 Elements for a Public Summary

VI.2.1 Overview of Disease Epidemiology

Male pattern baldness is a common type of hair loss that develops in many men and in some women as they grow older. It is also called androgenetic alopecia. Almost all men have some hair loss by the time they reach their 60s. About three in ten men in their 30s and half of men in their 50s are quite bald. Some women also develop the same type of hair loss, mainly at the top of their head. Baldness in women is much more common after a woman's menstrual period stops permanently (menopause). About 13 in every 100 women have some baldness before menopause, rising to 75 in 100 women over the age of 65 years.

VI.2.2 Summary of Treatment Benefits

PROPECIA is prescribed for individuals with male pattern baldness.

Two main clinical studies have been done with PROPECIA in male pattern baldness which involved 1553 men, 18 to 41 years of age, who were given one of the 2 treatments:

- PROPECIA tablets (finasteride 1 mg)
- Tablets without any medicine (placebo)

Assessment was done by counting the hair on the top bald area of the head. In men who took PROPECIA, an increase in hair count was observed. PROPECIA also slowed hair loss and improved the appearance of the hair. In men who took the tablets without any medicine, hair loss continued.

VI.2.3 Unknowns Relating to Treatment Benefits

The 2 main clinical studies included 1553 adult men with male pattern baldness, of which 779 men received PROPECIA, and 774 received a placebo (tablet with no medicine). The men in these studies ranged in age from 19 to 41 years.

The studies did not include any women, children or adolescents, or men with baldness due to other causes. Whether PROPECIA can be used to treat baldness in patients in these groups is not known.

VI.2.4 Summary of Safety Concerns

Important Identified Risks

Table 1 Summary of Important Identified Risks

Risk	What is Known	Preventability
Contact with PROPECIA by oral use or through the skin during Pregnancy	If a woman who is pregnant with a male baby absorbs the active ingredient in PROPECIA after oral use or through the skin, it may cause the male baby to be born with abnormalities of the sex organs.	Women who are or may potentially be pregnant must not use PROPECIA. They should also not handle crushed or broken tablets of PROPECIA. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling as long as the tablets are not broken or crushed. If a woman who is pregnant comes in contact with the active ingredient in PROPECIA, a doctor should be consulted.
Women and children 12-17 years old taking PROPECIA	The condition for which PROPECIA is prescribed occurs only in men.	Women and children/adolescents should not take PROPECIA.

Important Potential Risks

Table 2 Summary of Important Potential Risks

Risk	What is Known
Problems with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) which may continue after stopping the medication	Problems with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) which may continue after stopping the medicine have been reported with use of marketed PROPECIA. In the clinical studies, these problems resolved after stopping the medicine.
Male Infertility	Male infertility and/or poor quality of the semen has been reported during use of marketed PROPECIA. Normalization or improvement in the quality of the semen has been reported after stopping the medication. Men who were planning to father a child were excluded from the clinical studies. Studies in animals have not found negative effects on fertility that are relevant to humans.
Depressive Disorders	Depressed mood has been reported during use of marketed PROPECIA. In the clinical studies, there was no difference in the occurrence of depression when men who received PROPECIA were compared to those who received placebo.
Male Breast Cancer	Rare cases of breast cancer have been reported in men taking marketed PROPECIA. There were no cases of male breast cancer in the PROPECIA clinical studies.

Important Missing Information

Table 3 Summary of Important Missing Information

Missing Information	What is Known
None	

VI.2.5 Summary of Risk Minimization Measures by Safety Concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, along with the risks of the medicine and recommendations for minimizing these risks. An abbreviated version of this in lay language is provided in the form of the Package Leaflet (PL). The measures in these documents are known as routine risk minimization measures.

This medicine has no additional risk minimization measures.

VI.2.6 Planned Post-authorization Development Plan

VI.2.6.1 List of Studies in Post-authorization Development Plan

Table 4 List of Studies in Post-Authorization Development Plan

Study / Activity (including study number)	Objectives	Safety Concern(s) / Efficacy Issue(s) Addressed	Status	Planned Date for Submission of (Interim and) Final Results
A multinational, observational registry-based study on a potential link between finasteride and male breast cancer in 4 Nordic countries (Study #1, Stage #1)	Determine if male breast cancer occurs more often in men who have used finasteride than in men who have not used finasteride.	Male breast cancer	Completed	Interim report completed: 16-NOV-2012
Finasteride and male breast cancer – a register-based nested case-control study in Denmark, Finland, Norway and Sweden (Study #1, Stage # 2)	Determine what factors might or do make male breast cancer *appear* to occur more often in finasteride users than in finasteride non-users, assuming finasteride does not cause male breast cancer. Sometimes, a disease might appear to occur more often in one group of persons than another group of persons, but the actual cause of the disease is equally present in both groups.	Male breast cancer	Ongoing	2Q 2018

VI.2.6.2 Studies Which Are a Condition of the Marketing Authorization

The above study is not a condition of the marketing authorization.

VI.2.7 Summary of Changes to the Risk Management Plan Over Time

Table 5 Major Changes to the Risk Management Plan

RMP Version	Date	Safety Concerns	Comment
1.0	**31-DEC-2009**	**Summary—Ongoing Safety Concerns** **Important Identified Risks** Contact with PROPECIA by oral use or through the skin during Pregnancy Women and children 12-17 years old taking PROPECIA **Important Potential Risks** Inability to have an erection, which may continue after stopping the medication Male Infertility Depression **Important Missing Information** None	First risk management plan submission
1.1	**10-FEB-2009**	**Important Potential Risk** Male breast cancer	The main focus of the RMP update was to include the new important potential risk of male breast cancer.
2.0	**06-OCT-2011**	No changes to the safety concerns	The focus of the RMP update was to reflect an update of the PROPECIA SPC section 4.8 regarding depressive disorders, and the implementation of a questionnaire to further characterize this adverse event in patients on PROPECIA.
3.0	**03-OCT-2012**	No changes to the safety concerns	The main focus of this RMP update was to update information regarding the questionnaire and new information about the Male breast cancer study.
4.0	**22-NOV-2016**	**Important Potential Risks** Problems with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) which may continue after stopping the medication	The main focus of this RMP update was to include current information about the male breast cancer study. In addition, the potential risk of Inability to have an erection, which may continue after stopping the medication was updated to Problems

Table 5 Major Changes to the Risk Management Plan

RMP Version	Date	Safety Concerns	Comment
			with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) which may continue after stopping the medication
4.1	**25-APR-2017**	**Important Potential Risks** Problems with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) which may continue after stopping the medication	The potential risk of problems with sexual function (inability to have an erection, problems with ejaculation, decreased sex drive) was updated to clarify that they may continue after stopping PROPECIA.