

## PART III: CONSUMER INFORMATION

### <sup>Pr</sup>FINASTERIDE Finasteride tablets, BP

This leaflet is part III of a three-part "Product Monograph" published when FINASTERIDE 1 mg was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FINASTERIDE 1 mg. Contact your physician or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

**FINASTERIDE 1 mg IS FOR USE BY MEN ONLY.**

#### What the medication is used for:

FINASTERIDE 1 mg is used for the treatment of male pattern hair loss (also known as androgenetic alopecia).

#### What it does:

FINASTERIDE 1 mg blocks an important enzyme (Type II 5-alpha reductase) involved in the regulation of the hair follicle and lowers the levels of dihydrotestosterone (DHT) in the scalp, a major cause of male pattern hair loss.

#### When it should not be used:

Do not take FINASTERIDE 1 mg if you think you are allergic to any of its ingredients.

Women and children should not take FINASTERIDE 1 mg. Do not take FINASTERIDE 1 mg if you are or may potentially be pregnant (see WARNINGS AND PRECAUTIONS, Pregnancy).

#### What the medicinal ingredient is:

finasteride

#### What the important nonmedicinal ingredients are:

Cellulose microcrystalline, docusate sodium, lactose monohydrate, magnesium stearate, opadry brown 20A565004, sodium starch glycolate and starch pregelatinised.

#### Coating Ingredients:

Opadry brown 20A565004:  
It contains hypromellose, hydroxy propyl cellulose, talc, titanium dioxide, red iron oxide, & yellow iron oxide.

#### What dosage form it comes in:

1 mg Tablets: Brown colored, film coated, biconvex, octagonal shaped tablets, debossed with 'J' on one side and '81' on the other side. Available in blister pack of 4 x 7 tablets and HDPE bottles of 30, 100 & 1000 tablets.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use FINASTERIDE 1 mg talk to your physician or pharmacist** about any medical problems you have or have had, especially liver disease, and about any allergies.

Finasteride 5 mg (5 times the dose of FINASTERIDE 1 mg) may increase the chance of a more serious form of prostate cancer.

#### Pregnancy

Women who are or may potentially be pregnant must not use FINASTERIDE 1 mg. They should also not handle crushed or broken tablets of FINASTERIDE 1 mg. If the active ingredient in FINASTERIDE 1 mg is absorbed after oral use or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs. FINASTERIDE 1 mg tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed. If a woman who is pregnant comes into contact with the active ingredient in FINASTERIDE 1 mg, a physician should be consulted.

#### INTERACTIONS WITH THIS MEDICATION

FINASTERIDE 1 mg usually does not interfere with other medicines. However, you should always tell your physician about all medicines you are taking or plan to take, including those obtained without prescription.

**FINASTERIDE 1 mg can affect a blood test called PSA (prostate-specific antigen) used for the screening of prostate cancer. If you have a PSA test done, you should tell your physician that you are taking FINASTERIDE 1 mg.**

#### PROPER USE OF THIS MEDICATION

Take FINASTERIDE 1 mg as your physician has prescribed.

**Usual dose:** Take one tablet of FINASTERIDE 1 mg every day, with or without food.

**IMPORTANT: PLEASE READ**

**Missed Dose:** If you miss a dose, do not take an extra one. Just take the next tablet as usual.

**Overdose:**

If you think you have taken too much FINASTERIDE 1 mg, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**When can I expect to see results from using FINASTERIDE 1 mg?**

Male pattern hair loss is a condition that develops over a long period of time. On average, healthy hair grows only about 1 cm each month. Therefore, it will take time to see any effect. In general, daily use for three months or more may be necessary before you notice that hair growth is increased or further hair loss is prevented.

**How long do I need to use FINASTERIDE 1 mg?**

FINASTERIDE 1 mg can only work over the long term if you continue taking it.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like any medicine, FINASTERIDE 1 mg may cause side effects.

Common side effects

- less desire to have sex
- difficulty in achieving an erection.
- problems with ejaculation, such as a decrease in the amount of semen released during sex (this does not appear to interfere with normal sexual function).

In clinical studies, these side effects disappeared in men who stopped taking finasteride and in most men who continued treatment.

In general use, the following have been reported infrequently:

- breast enlargement (swelling) and/or tenderness;
- depression;
- decrease in sex drive that continued after stopping the medication;
- allergic reactions including rash, itching, hives, and swelling of the lips, tongue, throat and face;
- muscle injury, muscle pain, muscle weakness, abnormal test results (CK elevation).
- problems with ejaculation that continued after stopping the medication;
- testicular pain;

- blood in semen;
- difficulty in achieving an erection that continued after stopping the medication;
- male infertility and/or poor quality of semen. Improvement in the quality of semen has been reported after stopping the medication;
- male breast cancer,
- changes in mood, which can include suicidal thoughts.

Talk to your doctor about any changes in your breast such as lumps, pain or nipple discharge. Tell your physician or pharmacist promptly about these or any other unusual symptoms.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>Rare</b>	Allergic reactions including rash, hives, and swelling of the lips tongue, throat and face			√

*This is not a complete list of side effects. For any unexpected effects while taking FINASTERIDE 1 mg, contact your physician or pharmacist.*

**HOW TO STORE IT**

Store at room temperature (15°C to 30°C). Protect from moisture.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

## IMPORTANT: PLEASE READ

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### MORE INFORMATION

#### **If you want more information about FINASTERIDE 1 mg:**

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [www.sivem.ca](http://www.sivem.ca), or by calling 1-855-788-3153.

This leaflet was prepared by  
**Sivem Pharmaceuticals ULC**  
4705 Dobrin Street  
Saint-Laurent, QC, Canada  
H4R 2P7

Date of Revision: June 9, 2020