

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **P<sup>r</sup>FINASTERIDE**

#### **Finasteride tablets**

Read this carefully before you start taking **FINASTERIDE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FINASTERIDE**.

#### **What is FINASTERIDE used for?**

FINASTERIDE is used in adult men for the treatment of male pattern hair loss. This condition is also known as androgenetic alopecia.

#### **How does FINASTERIDE work?**

FINASTERIDE prevents the production of a hormone called DHT (dihydrotestosterone) in the scalp. DHT causes a decrease of hair growth and thinning of the hair. This can lead to male pattern hair loss. The lowered level of DHT in the scalp leads to increased hair growth.

#### **What are the ingredients in FINASTERIDE?**

Medicinal ingredient: finasteride

Non-medicinal ingredients:

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, red iron oxide, talc, titanium dioxide & yellow iron oxide.

#### **FINASTERIDE comes in the following dosage forms:**

Tablet 1 mg

#### **Do not use FINASTERIDE if:**

- you are allergic to finasteride, any ingredient in FINASTERIDE or component of its container.

- are a women or child. Women who are or may potentially be pregnant must not use FINASTERIDE.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FINASTERIDE. Talk about any health conditions or problems you may have, including if you:**

- have liver disease

**Other warnings you should know about:**

#### Monitoring and testing

- FINASTERIDE may increase your chance of a more serious form of prostate cancer. You may undergo a blood test called Prostate-Specific Antigen (PSA) test. The PSA test is for the screening of prostate cancer. FINASTERIDE can alter PSA values. If you have a PSA test done, you should tell the healthcare professional administering the test that you are taking FINASTERIDE.
- Your healthcare professional will check your PSA levels during your treatment.
- You should monitor your breasts regularly. Speak to your healthcare provider immediately if you notice any changes. This may include lumps, pain or nipple discharge, breast enlargement, and tenderness.

#### Pregnancy

- Women who are or may be pregnant must not use FINASTERIDE.
- They should also not handle crushed or broken tablets of FINASTERIDE. A male baby may be harmed if a pregnant woman is exposed to the medicinal ingredient in FINASTERIDE. It may cause the male baby to be born with abnormalities of the sex organs. A pregnant woman may be exposed if the tablet is absorbed through the skin. FINASTERIDE tablets are coated to prevent contact with the medicinal ingredient during normal handling (i.e. tablets are not broken or crushed).
- Speak to a healthcare professional if a pregnant woman comes into contact with the active ingredient in FINASTERIDE.

#### Behaviour and mood changes

- There have been reports that FINASTERIDE may cause changes in mood including extreme sadness (depression), injuries from hurting yourself on purpose (self-harm injury), and thoughts of suicide (suicidal ideation). These mental health problems may continue even after you stop treatment.

- Tell your healthcare professional if you have had these behaviour and mood changes before. They should check your mental health before, during and after your treatment with FINASTERIDE.
- If you feel sad, want to hurt yourself, or end your own life or if others around you notice changes in your behaviour, get medical help right away.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take FINASTERIDE:**

- Take FINASTERIDE exactly as your healthcare professional has prescribed.
- Take by mouth with or without food.

**Usual dose:**

Take one 1 mg tablet once a day.

**Overdose:**

If you think you, or a person you are caring for, have taken too much FINASTERIDE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed dose:**

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

**What are possible side effects from using FINASTERIDE?**

These are not all the possible side effects you may have when taking FINASTERIDE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- blood in semen;
- breast swelling and/or tenderness;
- difficulty in achieving an erection that continued after stopping the medication;
- difficulty in achieving an erection;

- less desire to have sex;
- male infertility;
- muscle injury, muscle pain, muscle weakness, abnormal test results (CK elevation);
- problems with ejaculation, such as a decrease in the amount of semen released during sex;
- testicular pain.

Serious side effects 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>UNCOMMON</b>			
<b>Behaviour and mood changes:</b> a sad mood that gets worse or doesn't go away, extreme sadness (depression)		✓	
<b>Self-harm behaviours:</b> injuries from deliberately hurting oneself (self-harm), thought of ending one's life (suicidal ideation)			✓
<b>RARE</b>			
<b>Allergic reactions:</b> hives, itching, rash, and swelling of the lips, tongue, throat and face			✓
<b>Male breast changes:</b> lumps, pain or nipple discharge		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### 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.

*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.*

**Storage:**

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

Keep out of reach and sight of children.

**If you want more information about FINASTERIDE:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); 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.

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