

## **Package leaflet: Information for the user**

### **Profal 5 mg film coated tablets**

Finasteride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Profal is and what it is used for
2. What you need to know before you take Profal
3. How to take Profal
4. Possible side effects
5. How to store Profal
6. Contents of the pack and other information

#### **1. What Profal is and what it is used for**

Profal contains the active substance finasteride which belongs to a group of medicines called ‘5-alpha reductase inhibitors’. They act by reducing the size of the prostate gland in men.

Profal is used in the treatment and control of benign (not cancerous) enlargement of the prostate.

#### **2. What you need to know before you take Profal**

##### **Do not take Profal:**

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman or a child (see also ‘Pregnancy and breast-feeding’ in this section).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Profal

- if you have reduced liver function.
- if you have difficulty emptying your bladder completely or a greatly reduced flow of urine, your doctor should examine you thoroughly before you start taking Profal to exclude other obstructions in the urinary tract.
- if you notice any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer. You should promptly report to your doctor if you notice any of these changes.

If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug (see also ‘Pregnancy and breast-feeding’ in this section).

If you need to have a blood test called “PSA”, make sure you tell your doctor or nurse first since finasteride may alter the results of the test.

##### **Mood alterations and depression**

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Profal. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.

#### **Other medicines and Profal**

Profal tablets can normally be taken with other medicines. Please ask your doctor before you take other medicines at the same time.

Tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines.

#### **Profal with food and drink**

Profal can be taken with or without food.

#### **Pregnancy and breast-feeding**

Profal is only intended for men.

If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug.

**Women who are pregnant or may become pregnant should not handle broken or crushed Profal tablets.** If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male fetus, the child may be born with malformed genital organs. The tablets are film-coated, which prevents contact with finasteride provided the tablets are not broken or crushed.

#### **Driving and using machines**

There is no evidence to suggest that Profal affects the ability to drive or use machines.

#### **Profal contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Profal**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 tablet daily.

The tablet should be swallowed whole and should not be broken or crushed. It may be taken with or without food.

#### **If you take more Profal than you should**

Immediately contact a doctor, the nearest hospital casualty department or the centre for poison information for advice.

#### **If you forget to take Profal**

Do not take a double dose to make up for a forgotten tablet. Just take the next one when it is due.

#### **If you stop taking Profal**

Although an improvement is often noticed after a short time, it may be necessary to continue the treatment for at least 6 months. Do not alter the dose or stop treatment without asking your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Profal and immediately contact your doctor if you experience any of the following symptoms: Swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties. These symptoms can be signs of an allergic reaction, including angioedema, which is reported as not known (frequency cannot be estimated from the available data).

Common (affects 1 to 10 users in 100):

Inability to obtain an erection, reduced sex drive, reduced ejaculatory volume.

Uncommon (affects 1 to 10 users in 1,000):

Tenderness of the breasts, skin rash, breast enlargement, difficulty obtaining ejaculation.

Not known (frequency cannot be estimated from the available data):

Depression, testicular pain, inability to obtain an erection even after stopping treatment with Profal, reduced sex drive that continued after stopping treatment, male infertility and/or poor quality of semen, itching, urticaria (hives), irregular, hard, or rapid heartbeat, increase in liver enzymes, anxiety.

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

## **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Profal**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Profal contains**

- The active substance (the ingredient which makes the medicine work) is finasteride. One film-coated tablet contains 5 mg finasteride.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose, pregelatinised starch (maize), lauroyl macroglycerides, sodium starch glycolate, magnesium stearate. The tablet coating contains hypromellose, macrogol, titanium dioxide (E171) and indigo carmine aluminium lake (E132).

### **What Profal looks like and contents of the pack**

Profal is a blue, round, biconvex tablet marked "F5". The diameter is 7 mm.

Blister packs containing 7, 10, 14, 20, 28, 30, 49, 50, 60, 98, 100 or 300 tablets.

Plastic bottles containing 10, 30, 50, 100 or 300 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd,  
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## **Manufacturer**

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IS-220 Hafnarfjörður  
Iceland

Genericon Pharma GmbH  
Hafnerstrasse 211  
A-8054 Graz  
Austria

Actavis Group PTC ehf  
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