

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

# Finasteride Teva

## Film-coated Tablets

### Composition:

Each film-coated tablet contains: Finasteride 1 mg

For information on inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

### Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

**The medicine is intended for use in men only and is not intended for use in women or children.**

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Finasteride Teva is intended to increase scalp hair growth and prevent further hair loss in men with male pattern hair loss (androgenetic alopecia).

**Therapeutic group:** 5-alpha reductase inhibitors.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- You are a woman (because this medicine is intended for men). Clinical trials have shown that finasteride is not effective as a treatment for women suffering from hair loss.
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 – "Further Information").
- You are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

Do not take Finasteride Teva if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

#### Special warnings regarding use of the medicine:

Talk to your doctor or pharmacist before taking Finasteride Teva if:

- You are about to perform a blood test for prostate cancer called PSA (prostate-specific antigen). This is because Finasteride Teva can affect the result of this test.

#### Breast Cancer:

See section 4 – "Side Effects".

#### Mood alterations and depression:

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

#### Children and adolescents:

Do not use Finasteride Teva in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

#### Drug Interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist** to prevent risks or inefficacy arising from drug interactions.

Finasteride does not usually affect other medicines.

- Do not take Finasteride Teva if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).
- There is no information regarding the use of finasteride with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

#### Use of the medicine and food:

Finasteride Teva can be taken with or without food.

#### Pregnancy, breastfeeding and fertility:

**Finasteride Teva is intended for the treatment of male pattern hair loss in men only.**

- Finasteride Teva is not intended to be taken by women.**
- Finasteride Teva is forbidden for use in women who are pregnant or may potentially be pregnant. Do not touch crushed or broken Finasteride Teva tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to prevent contact with the medicine during normal use). This is because this medicine may affect the baby's sex organs.**
- If a woman who is pregnant comes into contact with crushed or broken Finasteride Teva tablets, speak to your doctor.

#### Effects on fertility:

Infertility has been reported in men who took finasteride for a long time and had other risk factors that may affect fertility. Normalization and improvement of seminal quality has been reported after discontinuation of finasteride. Long-term clinical studies about the effects of finasteride on fertility in men have not been conducted.

#### Important information about some of the ingredients of the medicine:

Finasteride Teva contains **lactose**. If you have been told by your doctor that you have an intolerance to certain sugars, consult the doctor before taking the medicine. Finasteride Teva contains less than 1 mmol sodium (23 mg) per tablet and is therefore considered 'sodium-free'.

#### Driving and using machines:

Finasteride Teva is not likely to affect your ability to drive, use tools or machines.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally: one tablet by mouth, every day.

#### Instructions for use:

Swallow the tablet with a small amount of water, with or without food.

The tablet cannot be halved in the absence of a score line.

There is no information regarding crushing/chewing the tablet.

See also section 2 – "Pregnancy, breastfeeding and fertility".

#### Do not exceed the recommended dose.

Finasteride Teva will **not** work faster or better if you take it more than once a day.

You may need to take Finasteride Teva daily for three months or more before you notice the benefit of taking Finasteride Teva. Finasteride Teva can work in the long run only if you continue to take it. If the medicine has not had an effect on you within 12 months, further treatment is unlikely to be of benefit.

Finasteride Teva is not effective in treating balding in post-menopausal women (androgenetic alopecia).

#### If you accidentally take a higher dosage:

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed to a hospital emergency room and bring the package of the medicine with you.

#### If you forgot to take the medicine:

If you forgot to take Finasteride Teva, do not take another tablet. Take the next tablet as usual.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor.

#### If you stop taking the medicine:

If you stop taking Finasteride Teva, it is likely that you will lose the hair that grew within 12 months of discontinuing the treatment.

Discuss this with your doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult a doctor or pharmacist.**

### 4. SIDE EFFECTS

As with any medicine, use of Finasteride Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

#### Stop taking Finasteride Teva and talk to your doctor if you experience:

- Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking Finasteride Teva and talk to your doctor immediately.
- Depression (feeling of deep sadness and unworthiness).

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

#### Uncommon side effects – effects that occur in 1-10 out of 1,000 users:

- You may be unable to reach an erection (impotence).
- You may have decreased sexual drive.
- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

#### Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Breast swelling or tenderness.
- Palpitations (feeling your heartbeat).
- Changes in the way your liver is working, which can be shown by a blood test.
- Pain in the testicles.
- Presence of blood in semen.
- Difficulty reaching an erection that also continues after discontinuation of use of the medicine.
- Decreased sexual drive that also continues after discontinuation of use of the medicine.
- Problems with ejaculation that also continue after discontinuation of use of the medicine.
- Male infertility and/or poor quality of semen.
- Anxiety.
- Suicidal thoughts.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

#### Will the use of Finasteride Teva affect the hair on other parts of your body?

Finasteride Teva does not affect hair on other parts of the body.

#### What else should you know about Finasteride?

Finasteride can also be used for a type of prostate problem called "benign prostatic hyperplasia" or BPH. Information collected from a clinical trial in men taking finasteride 5 mg (a dose 5 times higher than Finasteride Teva 1 mg) for 7 years showed:

- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.
- The number of men who had a high score in a tumor grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumors of this kind is unknown.

If you would like further information about the tumor grading system or this trial, please talk to your doctor.

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

### 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, like any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor! Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

**Storage conditions:**  
**Store in a dry place, below 25°C.**

### 6. FURTHER INFORMATION

**In addition to the active ingredient, the medicine also contains:**

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, pregelatinized starch, povidone, magnesium stearate, sodium lauryl sulfate, hypromellose, titanium dioxide (E171), macrogol, iron oxide red (E172), iron oxide yellow (E172).

#### What the medicine looks like and what are the contents of the package:

Brown, round film-coated tablet, debossed "FNT 1" on one side and plain on the other.

Amount per package: 28, 30 or 100 film-coated tablets. Not all package sizes may be marketed.

**Name of Manufacturer and License Holder and Address:**  
Teva Israel Ltd.,  
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140.59.31427

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