

# PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription

## Dutasteride Taro Soft Capsules

Each soft capsule contains: 0.5 mg dutasteride.

A list of the additional ingredients is available in section 6, and in section 2: 'Important information about some of this medicine's ingredients'.

### Read the entire leaflet carefully before using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist.

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

This medicine is intended only for men.

### 1. What is this medicine intended for?

- Treating moderate to severe symptoms of benign enlargement of the prostate gland (BPH).
- Reducing the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of benign enlargement of the prostate gland.

**Dutasteride Taro is used to treat men with an enlarged prostate gland** (benign enlargement of the prostate gland) - a non-cancerous tumor of the prostate gland caused by over-production of a hormone called dihydrotestosterone.

Enlargement of the prostate gland can lead to problems in the urinary system, such as difficulty passing urine and needing to use the facilities frequently. It may, in addition, slow down and weaken urine flow. Without treatment, your urine flow could become completely blocked (*acute urinary retention*). This condition requires immediate medical treatment. In certain cases the prostate gland will have to be removed or made smaller. Dutasteride Taro reduces production of dihydrotestosterone, and in this way helps shrink the prostate gland and relieve the symptoms. This reduces the risk of acute urinary retention and the need for surgery.

Dutasteride Taro can also be used with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate gland).

### Therapeutic group

5-alpha reductase inhibitors.

### 2. Before using this medicine

#### Do not use this medicine if:

- you are sensitive (allergic) to Dutasteride Taro or to other inhibitors of the enzyme 5-alpha reductase, to soy, peanuts, or any of the other ingredients that this medicine contains and that are listed in section 6.

- you have a severe liver disease.

→ if you think that any of these apply to you, do not take this medicine and tell your doctor.

**This medicine is only for men!** It must not be taken by women, children, or adolescents.

### Special warnings regarding the use of this medicine

Talk to your doctor before you start taking this medicine.

- **Make sure your doctor knows whether you have liver problems.** If you have had any disease that affected your liver, you may need to have additional tests while you are taking Dutasteride Taro.

- **Women, children and adolescents** must avoid contact with Dutasteride Taro capsules that are leaking, because the active ingredient can be absorbed through the skin. So, if there is any contact with skin, **wash the area immediately** with soap and water.

- **Use a condom during sexual intercourse.** Dutasteride Taro was found in the semen of men who were taking the medicine. If your partner is pregnant or might be pregnant, you must avoid exposing her to your semen because Dutasteride Taro may affect the normal development of a male fetus. Dutasteride Taro has been found to reduce sperm count, sperm fluid volume, and sperm motility. This could reduce your fertility.

- **Dutasteride Taro affects the blood test for PSA** (Prostate Specific antigen) which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use this test to detect prostate cancer. If you undergo a PSA blood test, tell your doctor that you are taking Dutasteride Taro. **Men who are taking Dutasteride Taro must have their PSA tested regularly.**

- In a clinical study of men at increased risk of prostate cancer, men taking Dutasteride Taro developed a serious **form of prostate cancer more often** than men who did not take Dutasteride Taro. The effect of Dutasteride Taro on this serious form of prostate cancer is not well clear.

- **Dutasteride Taro may cause breast enlargement or breast tenderness.** If this becomes troublesome, or if you notice **lumps in your breast or a discharge from your nipple** talk to your doctor about these changes because they could be a sign of a serious medical problem such as breast cancer.

→ **Consult your doctor or pharmacist** if you have any questions about taking Dutasteride Taro.

**If you are taking, or have recently taken, any other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking certain medicines that may interact with Dutasteride Taro, because you may be likelier to experience side effects.** Some of these medicines are:

- **verapamil** or **diltiazem** (for high blood pressure)
- **ritonavir** or **indinavir** (for HIV, the human immunodeficiency virus)
- **itraconazole** or **ketonazole** (for fungal infection)
- **nefazodone** (for depression)
- **alpha blockers** (for treating an enlarged prostate or high blood pressure)

→ **Tell your doctor** if you are taking any of these medicines. You may need to have your dose of Dutasteride Taro reduced.

### Using this medicine and food

Dutasteride Taro can be taken with or without food.

### Pregnancy, breastfeeding, and fertility

**Pregnant women (or women might be pregnant) must not come into contact with leaking capsules.** Dutasteride Taro is absorbed through the skin and may affect the normal development of a male fetus. This risk is higher during the first 16 weeks of pregnancy.

**Use a condom during sexual intercourse.** Dutasteride Taro was found in the semen of men who were taking Dutasteride Taro. If your partner is pregnant or might be pregnant, you must avoid exposing her to your semen.

Dutasteride Taro has been found to reduce sperm count, semen volume, and sperm motility. So a man's fertility may be reduced.

→ Tell your doctor if a pregnant woman has come into contact with Dutasteride Taro.

### Driving and using machines

Dutasteride Taro is unlikely to affect your ability to drive or operate machines.

### Important information about some of this medicine's ingredients

#### Dutasteride Taro contains lecithin from soy

This medicine contains lecithin from soy which may contain soy oil. If you are allergic to peanuts or to soy, do not use this medicine.

### 3. How to use this medicine?

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

Only your doctor will determine your dose and how you should take this medicine.

**The recommended dose is one capsule (0.5 mg) taken once a day.**

Treatment with Dutasteride Taro is long-term. Some men will notice an early improvement in their symptoms. However, others will have to take Dutasteride Taro for 6 months or longer before the medicine begins to have an effect. Continue taking Dutasteride Taro for as long as your doctor tells you to.

#### Do not exceed the recommended dose.

Swallow the capsule whole with water. Do not chew, and do not open the capsule and release its contents. Contact with the contents of the capsule may cause pain in your mouth or throat.

**If you have accidentally taken a higher dose,** consult your doctor or pharmacist.

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

**If you forget to take this medicine** at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Continue taking this treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor. You may have to wait 6 months or longer before you feel the effect of this medicine.

If you do not take this medicine regularly, it may affect the monitoring of your PSA levels.

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

→ **If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### 4. Side effects

As with any medicine, using Dutasteride Taro may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

#### Allergic reaction

Signs of allergic reaction may include:

- **Rash** (may be itchy).
- **Hives** (similar to a rash from contact with nettles).
- **Swelling of the eyelids, face, lips, arms, or legs.**

→ Tell your doctor immediately if you notice any of these symptoms and **stop using Dutasteride Taro.**

#### Additional side effects

##### Common side effects

Side effects that occur in one out of 10 men taking Dutasteride Taro:

- Inability to achieve or maintain an erection (impotence); this effect can persist after you have stopped taking Dutasteride Taro.

- Reduced sex drive (libido); this effect can persist after you have stopped taking Dutasteride Taro.

- difficulty with ejaculation, such as a decrease in the amount of semen released during intercourse. This effect can persist after you have stopped taking Dutasteride Taro.

- Enlarged or tender breasts (gynecomastia).
- Dizziness when taken with tamsulosin.

##### Uncommon side effects

Side effects that occur in one out of 100 men taking Dutasteride Taro:

- Heart failure (The heart becomes less effective at pumping blood through the body. You may experience symptoms such as breathlessness, extreme tiredness, and swollen ankles and legs).
- Hair loss (usually body hair) or hair growth.

##### Side effects with unknown frequency

- Depression.
- Pain and swelling in your testes.

→ If you experience any side-effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also follow this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package to protect from light.

### 6. Additional information

In addition to the active ingredient, this medicine also contains: Propylene glycol monocaprylate, butylhydroxytoluene, gelatin, glycerol, titanium dioxide, triglycerides medium chain, lecithin soy.

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

Dutasteride Taro soft gelatin capsules are elongated, light yellow, and filled with a clear liquid. They are available in packages of 10, 30, 50, 60, and 90 capsules.

Not all pack sizes may be marketed.

- Registration holder: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

- Manufacturer: Laboratorios Leon Farma, SA, Leon, Spain.

- This leaflet was reviewed and approved by the Ministry of Health in May 2018.

- Registration number of the medicine in the Ministry of Health National Drug Registry: 160-47-35162-00