Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Duprost

Hard capsules

Active ingredients
Each capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride.

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult 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 for men only.

1. What is this medicine intended for?

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

Therapeutic group: Duprost is a combination of two different medicines called dutasteride and tamsulosin. Dutasteride belongs to a group of medicines called 5-alpha reductase inhibitors, and tamsulosin belongs to a group of medicines called alpha-blockers.

Duprost is used to treat men with an enlarged prostate gland (benign prostatic hyperplasia) - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.
Growth of the prostate gland can lead to urinary tract problems such as difficulty in passing urine and a need to go to the toilet frequently. It can also cause the flow of the urine to be slower and less forceful. Without treatment, there is a risk that urine flow will be completely blocked (acute urinary retention). This condition requires immediate medical treatment. Sometimes surgery is necessary to remove or reduce the size of the prostate gland.
Dutasteride lowers the production of the hormone called dihydrotestosterone, which helps shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery. Tamsulosin acts by relaxing the muscles in the prostate gland, making it easier to pass urine and rapidly improving the symptoms.

2. Before using this medicine

Do not use Duprost:

- **if you are sensitive (allergic) to the active ingredients dutasteride and tamsulosin hydrochloride, to other 5-alpha reductase inhibitors, soya, peanuts** or to any of the additional ingredients contained in the medicine (as listed in section 6).
- **in women** (as the medicine is intended for men only).
- **in children or adolescents under the age of 18.**
- **if you have low blood pressure** that makes you feel dizzy, lightheaded or faint (orthostatic hypotension).
- **if you have severe liver disease.**

➔If you think any of these apply to you, do not take the medicine until you have checked it with your doctor.

Special warnings about using this medicine

Talk to your doctor before you take Duprost.

- In some clinical studies, more patients taking dutasteride and another medicine called an alpha-blocker, like tamsulosin, experienced heart failure than patients taking only dutasteride or only an alpha-blocker. Heart failure means your heart does not pump blood as required.
- **Make sure your doctor knows if you have liver problems.** If you have had any illness that affected your liver, you may need to have additional tests while you are taking Duprost.
- **Make sure your doctor knows if you have severe kidney problems.**
- **Cataract (cloudy lens) surgery.** If you are going to have surgery to remove a cataract, your doctor may ask you to stop taking Duprost for a certain period of time before the operation. Tell the ophthalmologist before the operation that you are taking Duprost or tamsulosin (or have previously taken these medicines). The ophthalmologist will need to take the appropriate precautions to help prevent complications during the operation.
- **Women, children and adolescents** must avoid contact with leaking Duprost capsules, because the active ingredient can be absorbed through the skin. **Wash the affected area immediately** with soap and water if there is any contact with the skin.
- **Use a condom during sexual intercourse.** Dutasteride has been found in the semen of men taking Duprost. If your partner is or may be pregnant, you must avoid exposing her to your semen as dutasteride may affect the normal development of a male fetus. Dutasteride has been found to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.
- **Duprost affects a blood test for PSA (**prostate-specific antigen), which is sometimes used to detect prostate cancer. The doctor should be aware of this effect and can still use the test to detect prostate cancer. If you are having a blood test for PSA, tell the doctor that you are taking Duprost. **Men taking Duprost should have their PSA tested regularly.**

- In a clinical study of men at increased risk of prostate cancer, men who took dutasteride developed a **severe form of prostate cancer more often** than men who did not take dutasteride. The effect of dutasteride on this serious form of prostate cancer is not clear.
- **Duprost may cause breast enlargement and tenderness.** If this becomes troublesome, or if you notice **breast lumps** or **nipple discharge**, you should talk to your doctor about these changes as these may be signs of a serious medical problem such as breast cancer.

Contact your doctor or pharmacist if you have any questions about taking Duprost.

Children and adolescents
Do not use Duprost in children and adolescents under the age of 18.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Do not take Duprost with the following medicines:
- **other alpha-blockers** (for treatment of an enlarged prostate or high blood pressure)

Duprost is not recommended with the following medicines:
- **ketoconazole** (used to treat fungal infections)

Some medicines can react with Duprost, which may make it more likely that you will have side effects. These medicines include:
- **PDE5 inhibitors** (used to achieve or maintain an erection) such as vardenafil, sildenafil citrate and tadalafil
- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV - human immunodeficiency virus)
- **itraconazole or ketoconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **cimetidine** (for stomach ulcers)
- **warfarin** (for blood clots)
- **erythromycin** (an antibiotic used to treat infections)
- **paroxetine** (an antidepressant)
- **terbinafine** (used to treat fungal infections)
- **diclofenac** (used to treat pain and inflammation).

Tell your doctor if you are taking any of these medicines.

Using this medicine and food
Take Duprost 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility
Duprost is prohibited for use in women.

Pregnancy

Women who are pregnant (or who may be pregnant) must avoid contact with leaking capsules.

Dutasteride is absorbed through the skin and can affect the normal development of a male fetus. This risk is increased during the first 16 weeks of pregnancy.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Duprost. If your partner is or may be pregnant, you must avoid exposing her to your semen.

Tell your doctor if a pregnant woman has come into contact with Duprost.

Fertility

Duprost has been found to reduce sperm count, semen volume and sperm motility. Therefore male fertility may be reduced.

Driving and using machines

Duprost causes dizziness in some people, so it may affect your ability to drive or operate machinery safely.

Do not drive or operate machinery if you experience this effect.

Important information about some of this medicine's ingredients

Duprost contains the colouring agent Sunset yellow (E110), which is also called FD&C yellow 6, which may cause an allergic reaction.

Duprost contains lecithin from soya. If you are allergic to peanuts or soya, do not use this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

The standard dosage is generally one capsule taken once a day, 30 minutes after the same meal each day.

Do not exceed the recommended dose.

Swallow the capsule whole with water. Do not chew and do not open and disperse the contents of the capsule since contact with the contents of the capsule may cause pain in the mouth or throat.

Instructions for opening the bottle package - to remove the cap, press down, while simultaneously twisting to the left (counterclockwise).

Instructions for closing the bottle package - place the cap on top of the bottle opening and twist to the right (clockwise) until it completely closed.

If you have accidentally taken a higher dose
You should consult your doctor or pharmacist.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
Do not take a double dose to make up for the forgotten dose. Take the next dose at the usual time.

If you stop taking this medicine
Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.
If you do not take the medicine regularly, the monitoring of your PSA levels may be affected.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take 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 Duprost 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
The signs of an allergic reaction can include:
- **skin rash** (which can be itchy)
- **hives** (like a nettle rash)
- **swelling of the eyelids, face, lips, arms or legs.**

Tell your doctor immediately if you get any of these symptoms, **and stop using Duprost.**

Dizziness, lightheadedness and fainting
Duprost can cause dizziness, lightheadedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to a sitting or standing position, particularly if you wake up in the night, until you know how this medicine affects you. If you feel dizzy or lightheaded at any time during treatment, **sit or lie down until the symptoms pass.**

Serious skin reactions
The signs of serious skin reactions can include:
- **a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals** (Stevens-Johnson syndrome).

Contact your doctor immediately if you notice these symptoms and **stop using Duprost.**

Additional side effects
Common side effects - effects that occur in up to 1 in 10 users:
- impotence (not able to achieve or maintain an erection)*
- decreased sex drive (libido)*
- ejaculation dysfunctions such as a decrease in the amount of semen released during sex*
- tenderness or enlargement of the breast (gynecomastia)
- dizziness

* In a small number of people some of these effects may continue after discontinuation of Duprost.

Uncommon side effects - effects that occur in up to 1 in 100 users:
- heart failure (heart becomes less efficient at pumping blood around the body. You may have symptoms such as shortness of breath, extreme tiredness and swelling in ankles and legs)
- low blood pressure on standing
- fast heartbeat (palpitations)
- constipation, diarrhoea, vomiting, nausea
- weakness or lack of strength
- headache
- stuffy nose, itchy nose or runny nose (rhinitis)
- skin rash, hives, itching
- hair loss (usually from the body) or hair growth

Rare side effects - effects that occur in up to 1 in 1,000 users:
- swelling of the eyelids, face, lips, arms or legs (angioedema)
- fainting

Very rare side effects - effects that occur in up to 1 in 10,000 users:
- persistent painful erection
- serious skin reactions (Stevens-Johnson syndrome)

Side effects of unknown frequency
Other side effects have occurred in a small number of men, but their frequency is not known. (The frequency cannot be estimated from available data):
- irregular or fast heartbeat (arrhythmia or tachycardia or atrial fibrillation)
- shortness of breath
- depression
- pain and swelling in the testicles

- nosebleed
- severe skin rash
- vision changes (blurred or impaired vision)
- dry mouth

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.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.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 the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package.
  The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- **Shelf-life after opening the bottle pack:**
  Bottle pack of 30 capsules: Use within 6 weeks of first opening.
  Bottle pack of 90 capsules: Use within 18 weeks of first opening.
  Child-resistant package.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist about how to dispose of medicines you longer use. These steps will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Glycerol monocaprylocaprate type I, microcrystalline cellulose, gelatin, hypromellose, purified water, methacrylic acid - ethyl acrylate copolymer dispersion, glycerol, magnesium stearate, titanium dioxide (E171), red iron oxide (E172), purified talc, triacetin, carrageenan, potassium chloride, talc, yellow iron oxide (E172), sodium hydroxide, sunset yellow (E110), butylhydroxytoluene (BHT - E321), triglycerides (medium chain), lecithin (soya - E322).
What the medicine looks like and contents of the pack:
- An oblong, hard capsule with a brown body and orange cap, containing white-off white granules and a soft yellow gelatine capsule containing an oily yellow liquid.

The capsules come in packs of 7, 30 and 90 capsules in blisters or packs of 30 or 90 capsules in a bottle.
Not all pack types and sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Manufacturer's name and address: Galenicum Health S.L.U., Sant Gabriel, 50 08950 Esplugues de Liobregat, Barcelona, Spain

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 176-53-36974-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:

https://israeldrugs.health.gov.il/#!/medDetails/176%2053%2036974%2099

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.