

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

The medicine is dispensed with a doctor's prescription only

## **Tamsulosin Inovamed Prolonged-release film-coated tablets**

Each tablet contains:

Tamsulosin Hydrochloride 0.4 mg

For the list of inactive and allergenic ingredients in the preparation, see 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.**

- Keep the leaflet; you may need it again.
- This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

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

The medicine is intended to treat functional disorders of the lower urinary tract associated with benign prostatic hyperplasia.

**Therapeutic group:** Selective alpha<sub>1A,1D</sub> adrenoreceptor antagonist.

The active ingredient in the preparation reduces tension of the smooth muscles in the prostate and urethra, and enables urine to pass more readily through the urethra, thereby facilitating urination. In addition, it diminishes the feeling of urgency.

### **2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient tamsulosin or to any of the additional ingredients contained in the medicine. See section 6 – "Further information". Hypersensitivity may occur as sudden local swelling of the soft tissues of the body (e.g., the throat or tongue), breathing difficulties and/or itching and rash (angioedema).
- you suffer from severe liver problems.
- you suffer from fainting due to decreased blood pressure when changing posture, for example when transitioning to a standing or sitting position.

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

- Consult with the doctor before taking the medicine.
- In rare cases, as with other preparations from the same group, Tamsulosin Inovamed can cause fainting. When you suffer from dizziness or fainting, sit or lie down until the signs pass.

**Before treatment with Tamsulosin Inovamed, tell the doctor if:**

- You suffer from severe kidney problems.
- You are undergoing eye surgery for cataract, or surgery to treat intraocular pressure (glaucoma), inform the ophthalmologist that you are using the medicine, plan to use it or have used it in the past. When necessary, the ophthalmologist will take preventative measures (medicinal or surgical). Consult the attending doctor about discontinuing treatment with the medicine before cataract surgery or surgery to treat increased intraocular pressure.

**Children and adolescents:**

The medicine is not intended for children and adolescents below the age of 18, as the medicine is not effective in this population.

**Tests and follow-up:**

You should perform periodic medical examinations which are necessary for monitoring your medical condition.

**Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:

- Antihypertensive medicines from the same class (alpha adrenoreceptor blockers). The combination may cause an undesirable decrease in blood pressure.
- Medicines that may decrease clearance of the medicine Tamsulosin Inovamed from the body (e.g., ketoconazole and erythromycin).

**Use of the medicine and food:**

Tamsulosin Inovamed can be taken with or without food.

**Pregnancy, breastfeeding and fertility:**

Tamsulosin Inovamed is not intended for use in women.

In men, there have been reports of abnormal ejaculation (ejaculation disorders), namely, the semen does not leave the body via the urethra, but passes into the urinary bladder (retrograde ejaculation) or the ejaculate volume is reduced or disappears (ejaculation failure). This phenomenon is not harmful.

**Driving and operating machinery:**

There is no evidence that Tamsulosin Inovamed affects the ability to drive or to operate machinery that requires alertness. However, Tamsulosin Inovamed may cause dizziness, and therefore, you must be cautious when driving and/or operating machinery that requires alertness.

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

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about 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 per day, preferably at the same time every day.

**Do not exceed the recommended dose.**

**Crushing/splitting/chewing:**

Do not chew or crush the tablet! Swallow the medicine whole with a little water.

Remnants of the tablet may appear in the stools. Since the active ingredient has been released, the effectiveness of the medicine does not decrease.

**If you accidentally took a higher dosage,** it may lead to an undesirable drop in blood pressure, increased heart rate and feeling faint.

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

**If you forgot to take this medicine** at the required time, you can take Tamsulosin Inovamed later in the same day. If you forgot to take the medicine and missed a day of treatment, take the next dose at the usual time. Do not take a double dose.

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 the doctor or pharmacist.

If you stop taking the medicine earlier than recommended to you by the doctor, the medical problems may recur.

Always consult the doctor if you are considering discontinuing treatment.

**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 the doctor or pharmacist.**

### **4. SIDE EFFECTS**

As with any medicine, use of Tamsulosin Inovamed 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.

**Common side effects – effects that occur in 1-10 users in 100:**

- Dizziness, especially when suddenly transitioning to a sitting or standing position
- Abnormal ejaculation – this means that semen does not leave the body via the urethra, but rather goes into the urinary bladder (retrograde ejaculation), or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless

**Uncommon side effects – effects that occur in 1-10 users in 1,000:**

- Headache
- Heart palpitations (awareness of stronger than normal heartbeats)
- Decreased blood pressure accompanied by dizziness, e.g., when getting up quickly from a sitting or lying position
- Runny nose or nasal congestion (rhinitis)
- Constipation, diarrhea, nausea, vomiting
- Weakness (asthenia)
- Rash, itching, hives (urticaria)

**Rare side effects – effects that occur in 1-10 users in 10,000:**

- Feeling faint and sudden swelling of the soft tissues of the body (e.g., throat, tongue), breathing difficulties and/or itching and rash, sometimes as an allergic reaction (angioedema)

**Very rare side effects – effects that occur in less than one user in 10,000:**

- Priapism (an unwanted prolonged painful erection that requires medical treatment)
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome)

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

- Blurred vision
- Impaired vision
- Nose bleeds (epistaxis)
- Severe skin rash (erythema multiforme, exfoliative dermatitis)
- Irregular heart rhythm (atrial fibrillation, arrhythmias, tachycardia), breathing difficulties (breathlessness)
- If you are undergoing eye surgery for cataracts or surgery to treat increased intraocular pressure (glaucoma), and you are taking or have previously taken Tamsulosin Inovamed, a constricted non-dilating pupil may occur during surgery as well as a floppy iris (the colored part of the eye)
- Dry mouth

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

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 and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

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

**Storage conditions:** Store at a temperature below 25°C. Store in the original package to protect from light.

### **6. FURTHER INFORMATION:**

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

Hypromellose, Cellulose Microcrystalline, Carbomer, Silica Colloidal Anhydrous, Iron Oxide Red, Magnesium Stearate.

**What the medicine looks like and the contents of the package:**

Tamsulosin Inovamed tablets: White, unscored, round tablets with a diameter of 9 mm, debossed on one side with "T9SL" and "0.4" on the other side.

**Package sizes:** The tablets are packaged in plastic trays/blisters, which are packaged in carton boxes.

The number of tablets in a carton package may be either 28 or 30 tablets.

Not all pack sizes may be marketed.

**License holder and address:** Inovamed Ltd., 55 Beer Ganim St., P.O.B 62, Even Yehuda 40500.

**Name of Manufacturer and address:** Synthon B.V., Microweg 22, 6545 CM, Nijmegen, Netherlands.

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 151-99-33641