

**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 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: Alpha₁ adrenoceptor antagonist.

Tamsulosin Inovamed contains the active ingredient tamsulosin hydrochloride. It acts by relaxing the muscles in the prostate and urethra (the tube that carries the urine to the outside), and lets urine pass more readily through the urethra and aids urination.

In the prostate gland, bladder and urethra, there are specialized cells that contain alpha_{1A} receptors that cause the muscles in the urethra to tighten. Tamsulosin Inovamed is an alpha_{1A} receptor blocker, which reduces the action of these specialized cells and relaxes the muscles, making it easier to pass urine.

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".
- you suffer from severe liver problems.
- you have ever fainted or felt dizzy when suddenly sitting down or standing up. Dizziness can sometimes occur when taking Tamsulosin Inovamed, particularly if you are also taking other alpha₁ blockers. If you do feel weak or dizzy, make sure you sit or lie down immediately until the symptoms pass.

Special warnings regarding use of the medicine:

Before treatment with Tamsulosin Inovamed, tell the doctor:

- If you have kidney problems.
- If you are undergoing or are scheduled to undergo eye surgery due to cloudiness of the lens (cataract) or increased intraocular pressure (glaucoma).

Tell the eye doctor that you are using, plan to use or previously used the medicine. The eye doctor can then take appropriate precautions with respect to medicines and surgical techniques to be used. Consult the attending doctor about postponing or temporarily stopping 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.

Before starting and during treatment with this medicine, a rectal examination, and, if needed, a test to determine prostate-specific antigen (PSA) levels, should be performed.

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 if you are taking:

- Medicines to lower your blood pressure, such as: verapamil, diltiazem.
- Medicines to treat HIV, such as: ritonavir, indinavir.
- Medicines to treat a fungal infection, such as: ketoconazole, itraconazole.
- Other alpha blockers, such as: doxazosin, indoramin, alfuzosin, prazosin.
- Erythromycin, an antibiotic used to treat infections.
- Warfarin, anticoagulant.
- Diclofenac, nonsteroidal anti-inflammatory.

Before any surgery or dental procedure, inform your doctor that you are being treated with Tamsulosin Inovamed, as there is a potential that the medicine may interfere with the effects of the anesthetic.

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, cases of abnormal ejaculation have been reported (ejaculation disorders), meaning that the semen does not leave the body through the urethra but goes into the urinary bladder (retrograde ejaculation) or the ejaculation volume decreases or disappears (ejaculation failure). This phenomenon is harmless.

Driving and using machines:

There is no information available on whether Tamsulosin Inovamed affects the ability to drive or to operate machines or equipment. However, it is known that Tamsulosin Inovamed may cause drowsiness, blurred vision, dizziness and fainting. If you suffer from any of these, do not drive and/or operate 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 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, split 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 cause a severe decrease in blood pressure, dizziness and malaise. 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 return.

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.

Stop taking the medicine and consult a doctor immediately if any of the following conditions occur – you may need medical treatment:

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

- Swelling of the face, throat or tongue with breathing problems related to allergy

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

- Prolonged and painful erection, usually unrelated to sexual activity
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome)
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), breathing difficulties (breathlessness)

Additional side effects

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

- Dizziness
 - Abnormal ejaculation (ejaculation disorders) – meaning that the semen does not leave the body through the urethra but goes into the urinary bladder (retrograde ejaculation) or the ejaculation volume decreases or disappears (ejaculation failure). This phenomenon is harmless
- #### **Uncommon side effects – effects that occur in 1-10 users in 1,000:**
- Weakness
 - Headache
 - Runny or congested nose
 - Dizziness when you sit or stand up
 - Palpitations (rapid or irregular heart beat)
 - Gastrointestinal symptoms, such as: nausea and vomiting, diarrhea or constipation
 - Hypersensitivity reactions, such as: rash, itching, redness, local swelling and breathing difficulties

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

- Fainting

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

- Blurred vision
- Impaired vision
- Nose bleeds (epistaxis)
- Severe skin rashes (erythema multiforme, exfoliative dermatitis)
- Dry mouth
- If you are undergoing cataract surgery in the eyes or surgery to treat increased intraocular pressure (glaucoma), and you are taking, or have previously taken, Tamsulosin Inovamed, a constricted pupil effect called intraoperative floppy iris syndrome (IFIS), is possible during surgery

As with other medicines of this type, drowsiness, blurred vision or swelling of the hands and feet can occur.

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.

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) 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, magnesium stearate, iron oxide red.

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

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

Package sizes: The tablets are packaged in 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 importer: Inovamed Ltd., P.O.B 62, Even Yehuda.

Manufacturer: Synthon B.V., Nijmegen, Netherlands.

Revised in February 2025.

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