

UROTEx 4 MG FILM-COATED TABLET

Silodosin 4 mg

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What Urotex is used for

Urotex is used to treat the symptoms of benign prostatic hyperplasia (BPH, an enlarged prostate gland) in patients ≥ 50 years. The prostate gland is an organ found at the base of the bladder in men. When enlarged, it can cause problems with the flow of urine.

How Urotex works

The active substance in Urotex, silodosin, is an alpha-adrenoceptor antagonist. It works by blocking receptors called α_1A adrenoreceptors in the prostate gland, the bladder and the urethra (the tube that leads from the bladder to the outside of the body). When these receptors are activated, they cause the muscles controlling the flow of urine to contract. By blocking these receptors, silodosin allows these muscles to relax, making it easier to pass urine and relieving the symptoms of BPH.

Before you use Urotex

- When you must not use it

- If you are allergic (hypersensitive) to silodosin or any ingredients of Urotex.
- If you have low blood pressure
- If you have liver function problems
- If you have kidney failure

Children and adolescents

Urotex is not for use in children and adolescents as it has not been studied in patients under 18 years. Ask your doctor or pharmacist for advice before taking Urotex.

- Before you start use it

Before taking Urotex, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of:

- Low blood pressure
- Liver function problems
- Kidney failure
- Certain eye problems (cataracts, glaucoma)

Your doctor may want to see you more often and do some tests if you have any of these conditions.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor in particular, if you take:

- Medicines which lower blood pressure as there may be the potential risk that the effect of these medicines is increased whilst taking Urotex.
- Antifungal medicines (such as ketoconazole or itraconazole), medicines because these medicines can increase the blood concentration of Urotex.
- Medicines used for treating problems in getting or keeping an erection (such as sildenafil or vardenafil), since the concomitant use with Urotex might lead to a slight decrease in blood pressure.

How to use Urotex

- How much to use

Always take Urotex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 4 mg twice daily after breakfast and evening meal.

If you have the impression that the effect of Urotex is too strong or too

weak, talk to your doctor or pharmacist.

- When to use it

Try to take the Urotex tablet at the same time each day. Always take it after food. Always take the tablet with water and swallow it whole.

- How long to use it

Continue taking Urotex for as long as your doctor recommends.

Even if you feel better, do not discontinue it or alter the daily dose of Urotex without first consulting your doctor.

- If you forget to use it

If you miss a dose, take the missed dose as soon as you remember but do not take more than two doses in one day.

- If you use too much (overdose)

If you realise you have taken more Urotex than your doctor has recommended (or if someone else has taken some of your Urotex), contact your doctor or pharmacist right away.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Urotex.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give Urotex to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines Urotex may cause dizziness which may affect your ability to drive or use machinery. Do not drive or use any tools or machines, until you know how Urotex affects you. If you are affected you should not drive or use machinery.

Side effects

Like all medicines, Urotex can cause side effects, although not everybody gets them.

Some people may experience abnormal ejaculation, thirstiness, diarrhea or loose stools, dizziness, nose blocks and headaches.

In some people, it may cause a rise in liver function readings in the early stage: general malaise, poor appetite or jaundice.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Urotex

- Storage

Keep out of reach of children.

Store below 30°C and protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

White biconvex oval film coated tablet debossed with “S,4” and breakline on one side and plain on the other.

- Ingredients

- Active ingredient:

The active substance is silodosin.

Each tablet contains 4 mg of silodosin.

- Inactive ingredients:

Mannitol, Corn starch, Low-substituted hydroxypropyl cellulose, Hydroxypropyl cellulose type L, Talcum, Magnesium

stearate, Hydrogenated vegetable oil type I, Hypromellose, Polyethylene glycol 6000, Opadry white and Ethanol

- MAL number:

MAL*****

Manufacturer

Sriprasit Pharma Co., Ltd.
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Product Registration Holder

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