

Urief® FILM COATED TABLETS

Silodosin (4mg)

What is in this leaflet

1. What Urief is used for
2. How Urief works
3. Before you use Urief
4. How to use Urief
5. While you are using Urief
6. Side effects
7. Storage and Disposal of Urief
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Urief is used for

Urief 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 Urief works

The active substance in Urief, silodosin, is an alpha-adrenoceptor antagonist. It works by blocking receptors called alpha1A 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 Urief

- When you must not use it
 - If you are allergic (hypersensitive) to silodosin or any ingredients of Urief.
 - If you have low blood pressure
 - If you have liver function problems
 - If you have kidney failure

Children and adolescents

Urief 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 Urief.

- Before you start use it
Before taking Urief, 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 Urief.
- Antifungal medicines (such as ketoconazole or itraconazole), medicines because these medicines can increase the blood concentration of Urief.
- Medicines used for treating problems in getting or keeping an erection (such as sildenafil or vardenafil), since the concomitant use with Urief might lead to a slight decrease in blood pressure.

How to use Urief

- How much to use

Always take Urief 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 Urief is too strong or too weak, talk to your doctor or pharmacist.

- When to use it

Try to take the Urief 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 Urief for as long as your doctor recommends.

Even if you feel better, do not discontinue it or alter the daily dose of Urief 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 Urief than your doctor has recommended (or if someone else has taken some of your Urief), 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 Urief.

- Things you must not do

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

Urief 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 Urief affects you. If you are affected you should not drive or use machinery.

Side effects

Like all medicines, Urief 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. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Urief[®] FILM COATED TABLETS

Silodosin (4mg)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Date of revision

17/10/2019

Serial Number

NPRA (R1/1) 14102019/239

Storage and Disposal of Urief

- Storage

Keep out of the reach and sight of children.

Store at room temperature below 30°C. Protect from light.

Do not use Urief after the expiry date which is stated on the carton.

- 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

Urief 4 mg tablets are scored tablets that are white to pale yellowish white.

- Ingredients

- Active ingredient(s)

The active substance is silodosin. Each tablet contains 4 mg of silodosin.

- Inactive ingredients

The other ingredients are Hydroxypropylcellulose, Corn starch, Magnesium stearate, Talc, D-mannitol, Hypromellose, Titanium Oxide and Carnauba Wax

- MAL number(s):

MAL17117022ARZ

Manufacturer

Kissei Pharmaceutical Co., Ltd
19-48, Yoshino, Matsumoto City,
Nagano Prefecture, Japan

Product Registration Holder

Eisai (Malaysia) Sdn Bhd.
Unit 701D, Level 7, Tower D, Uptown 5,
No. 5, Jalan SS21/39, Damansara
Uptown,
47400 Petaling Jaya
Selangor, Malaysia