

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking UROREC?

UROREC contains the active ingredient silodosin. It is used in men for the relief of lower urinary tract symptoms associated with a medical condition called benign prostatic hyperplasia or BPH.

For more information, see Section [1. Why am I taking UROREC?](#) in the full CMI.

2. What should I know before I take UROREC?

Do not take if you are a woman or a child, or if you have ever had an allergic reaction to silodosin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I take UROREC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with UROREC and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take UROREC?

- The usual dose is one capsule of UROREC 8 mg taken once each day at about the same time. If you have moderate kidney problems, your doctor may start you on a lower 4 mg dose. Swallow the capsule whole, with or straight after food, with a glass of water.

More instructions can be found in Section [4. How do I take UROREC?](#) in the full CMI.

5. What should I know while taking UROREC?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking UROREC.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• If you are going to have eye surgery for cataracts, please tell your surgeon that you are taking or have ever taken UROREC.
Things you should not do	<ul style="list-style-type: none">• Do not take UROREC to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• UROREC may cause dizziness in some people. If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the pack until it is time to take them.• Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while taking UROREC?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: changes or problems with ejaculation (decrease in the amount of semen released during sex), dizziness, runny or blocked nose and diarrhoea. Serious side effects include: swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking UROREC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking UROREC.**

Where to find information in this leaflet:

1. [Why am I taking UROREC?](#)
2. [What should I know before I take UROREC?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take UROREC?](#)
5. [What should I know while taking UROREC?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking UROREC?

UROREC contains the active ingredient silodosin.

Silodosin belongs to a group of medicines called alpha-blockers. UROREC works by helping relax the smooth muscles in the prostate, in that way it improves flow of urine. This makes it easier for you to pass urine and relieves your symptoms.

UROREC is for use by men only. It is used for the relief of lower urinary tract symptoms associated with a medical condition called benign prostatic hyperplasia or BPH. BPH is a condition where the prostate gland (which is near your bladder) has become bigger making it more difficult for you to pass urine. This can lead to symptoms such as:

- weak or interrupted stream of urine
- feeling that you cannot empty your bladder completely
- delay before you start to pass urine
- needing to pass urine often, especially at night
- feeling that you must pass urine straight away.

BPH occurs only in men and is common over the age of 50 years. In some men, BPH can lead to serious problems, including urinary tract infections and the sudden inability to pass urine at all.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

UROREC is not addictive.

2. What should I know before I take UROREC?

Warnings

Do not take UROREC if:

- you are allergic to silodosin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

- you are a woman or a child.

The condition for which UROREC is prescribed occurs only in men.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- have any other medical conditions such as:
 - o severe liver problems
 - o kidney problems
 - o feeling dizzy or light-headedness when you sit up or stand abruptly
 - o prostate symptoms
Since a benign enlargement of the prostate and prostate cancer may present the same symptoms, your doctor will check you for prostate cancer before starting treatment with UROREC. **UROREC does not treat prostate cancer.**
 - o changes or problems with ejaculation
The treatment with UROREC may lead to an abnormal ejaculation (decrease in the amount of semen released during sex) that may temporarily affect male fertility. This effect normally disappears after discontinuation of UROREC. Please inform your doctor if you are planning to have children.
 - o planning to have eye surgery.

If you are undergoing eye surgery because of cloudiness of the lens (cataract surgery), it is important that you immediately inform your eye specialist that you are taking or have previously taken or about to start taking UROREC.

This is because some patients treated with this kind of medicine may experience a loss of muscle tone in the iris (the coloured part of the eye) during eye surgery.

The period of time between discontinuing the medicine and eliminating the risk of loss of muscle tone in the iris is unknown. It is important therefore that you tell your eye surgeon if you have ever taken UROREC. The surgeon can take appropriate precautions with respect to medicine and surgical techniques to be used.

Ask your eye specialist whether or not you should postpone or temporarily stop taking UROREC when undergoing cataract surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and UROREC may interfere with each other. These include:

- medicines which lower blood pressure (in particular, medicines called alpha-blockers, such as prazosin or doxazosin)
- antifungal medicines (such as ketoconazole or itraconazole)
- medicines used for HIV-AIDS (such as ritonavir)
- medicines used after transplants to prevent organ rejection (such as cyclosporine)
- medicines used for treating problems in getting or keeping an erection (such as sildenafil or tadalafil)
- medicines for epilepsy (such as carbamazepine and phenytoin)
- rifampicin (a medicine to treat tuberculosis).

These medicines may be affected by UROREC or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect UROREC.

4. How do I take UROREC?

How much to take

- The usual dose is one capsule of UROREC 8 mg taken once each day.
- Patients with kidney conditions:
- If you have moderate kidney problems, your doctor may start you on a lower dose. UROREC is also available as a 4 mg hard capsule.
- Follow the instructions provided and take UROREC until your doctor tells you to stop.

If you stop treatment, your symptoms may re-appear.

When to take UROREC

- Take your medicine at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take UROREC

- Swallow the UROREC capsule whole, with or straight after food, preferably with a glass of water.
- Do not break or chew the capsule.

If you forget to take UROREC

UROREC should be taken regularly at about the same time each day. If you miss your dose at the usual time take your dose as soon as you remember, continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you miss a whole day, continue to take your normal daily dose the next day.

Do not take a double dose to make up for the dose you missed.

If you take too much UROREC

If you think that you have taken too much UROREC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking UROREC?

Things you should do:

Remind any doctor, dentist or pharmacist you visit that you are taking UROREC.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking UROREC.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are going to have eye surgery for cataracts, please tell your surgeon that you are taking or have ever taken UROREC (see Section [6. Are there any side effects?](#))

Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do:

- Do not take UROREC to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how UROREC affects you.

UROREC may cause dizziness in some people

If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your capsules in the pack until it is time to take them. This will protect the capsules from light and moisture.

If you take the capsules out of the pack they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Very Common: <ul style="list-style-type: none">• changes or problems with ejaculation, such as decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function) Common <ul style="list-style-type: none">• dizziness• runny or blocked nose• diarrhoea Uncommon: <ul style="list-style-type: none">• decreased sexual drive• nausea• dry mouth• difficulties in getting or keeping an erection• fast heartbeats• skin rash, itchiness• hives (pinkish, itchy swellings on the skin)• abnormal liver enzyme levels• low blood pressure.	Speak to your doctor if you have any of these less serious side effects and they worry you

Less serious side effects	What to do
Rare: <ul style="list-style-type: none">• fast or irregular heartbeats (called palpitations)• fainting/loss of consciousness	

Serious side effects

Serious side effects	What to do
Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. These are symptoms of very rare serious allergic reaction. You may need urgent medical attention or hospitalisation	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

UROREC may cause complications during a cataract surgery.

Some patients treated with UROREC can experience a loss of muscle tone in the iris (the coloured circular part of the eye) during such a surgery.

It is important that you immediately inform your eye specialist if you are taking or have previously taken UROREC. The specialist can take appropriate precautions with respect to the medicine and surgical techniques to be used.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What UROREC contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• each UROREC 8 mg capsule contains 8 mg silodosin• each UROREC 4 mg capsule contains 4 mg silodosin
Other ingredients	<ul style="list-style-type: none">• pregelatinised maize starch• mannitol

(inactive ingredients)	<ul style="list-style-type: none"> • magnesium stearate • sodium lauryl sulfate • gelatin • titanium dioxide • iron oxide yellow (in UROREC 4 mg capsule only)
Potential allergens	UROREC does not contain lactose, sucrose or gluten

Do not take this medicine if you are allergic to any of these ingredients.

What UROREC looks like

UROREC 8 mg are white, opaque, hard gelatine capsules (AUST R 275265).

UROREC 4 mg are yellow, opaque, hard gelatine capsules (AUST R 275256).

Trade packs are available in blister packs of 30 capsules, and starter packs available in blister packs of 10 capsules.

Who distributes UROREC?

Mayne Pharma International Pty Ltd
1538 Main North Road
Salisbury South, SA 5106

This leaflet was prepared in May 2025.