

UROREC®

silodosin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about UROREC. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking UROREC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What UROREC is used for

UROREC is for use by men only.

UROREC 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.

This medicine 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 water and relieves your symptoms.

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.

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

Before you take UROREC

When you must not take it

Do not take UROREC if you have an allergy to:

- any medicine containing silodosin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are a woman or a child.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- severe liver problems
- kidney problems
- feeling dizzy or light-headedness when you sit up or stand abruptly
- 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.

- 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 disappears after discontinuation of UROREC. Please inform your doctor if you are planning to have children.

- 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 using or have previously used 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.

If you have not told your doctor about any of the above, tell him/her before you start taking UROREC.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take UROREC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to take it

Swallow the UROREC capsule whole, with or straight after food, preferably with a glass of water.

Do not break or chew the capsule.

When to take it

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 long to take it

Continue taking your medicine for as long as your doctor tells you.

If you stop treatment, your symptoms may re-appear. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to take it

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much UROREC. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking UROREC

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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 "Side effects")

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

Things you must 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.

Things to be careful of

Be careful driving or operating machinery while taking UROREC.

This medicine 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking UROREC.

Like all medicines, UROREC can cause some unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Very Common:

changes or problems with ejaculation, such as retrograde ejaculation or decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function).

Common

- dizziness
- runny or blocked nose
- diarrhoea.

Uncommon:

- decreased sexual drive
- nausea
- dry mouth
- difficulties in getting or keeping an erection
- fast heart beats
- skin rash, itchiness
- hives (pinkish, itchy swellings on the skin)
- abnormal liver enzyme levels
- low blood pressure.

Rare:

- fast or irregular heart beats (called palpitations)
- fainting/loss of consciousness.

The above list includes some serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also 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.

After taking UROREC

Storage

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.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store UROREC or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

- iron oxide yellow (in UROREC 4 mg capsule only).

UROREC does not contain lactose, sucrose or gluten.

Supplier

Mayne Pharma International Pty Limited

ABN 88 007 870 984

1538 Main North Road

Salisbury South SA 5106

Australian Registration Numbers

4 mg capsule: AUST R 275256

8 mg capsule: AUST R 275265

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Product description

What it looks like

UROREC 8 mg are white, opaque, hard gelatine capsules.

UROREC 4 mg are yellow, opaque, hard gelatine capsules.

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

Ingredients

Active ingredient:

- each UROREC 8 mg capsule contains 8 mg silodosin
- each UROREC 4 mg capsule contains 4 mg silodosin.

Inactive ingredients:

- pregelatinised maize starch
- mannitol
- magnesium stearate
- sodium lauryl sulfate
- gelatin
- titanium dioxide