

Package Leaflet: Information for the patient

Urorec 8 mg hard capsules
Urorec 4 mg hard capsules
Silodosin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Urorec is and what it is used for
2. What you need to know before you take Urorec
3. How to take Urorec
4. Possible side effects
5. How to store Urorec
6. Contents of the pack and other information

1. What Urorec is and what it is used for

What Urorec is

Urorec belongs to a group of medicines called alpha_{1A}-adrenoreceptor blockers.

Urorec is selective for the receptors located in the prostate, bladder and urethra. By blocking these receptors, it causes smooth muscle in these tissues to relax. This makes it easier for you to pass water and relieves your symptoms.

What Urorec is used for

Urorec is used in adult men to treat the urinary symptoms associated with benign enlargement of the prostate (prostatic hyperplasia), such as:

- difficulty in starting to pass water,
- a feeling of not completely emptying the bladder,
- a more frequent need to pass water, even at night.

2. What you need to know before you take Urorec

Do not take Urorec

if you are allergic to silodosin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Urorec

- 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 Urorec. This is because some patients treated with this kind of medicine experienced a loss of muscle tone in the iris (the coloured circular part of the eye) during such a surgery. The specialist can take appropriate precautions with respect to medicine and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking Urorec when undergoing cataract surgery.

- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking Urorec.
Dizziness when standing up and occasionally **fainting** may occur when taking Urorec, particularly when starting treatment or if you are taking other medicines that lower blood pressure. If this occurs, make sure you sit or lie down straight away until the symptoms have disappeared and inform your doctor as soon as possible (see also section “Driving and using machines”).
- If you have **severe liver problems**, you should not take Urorec, as it was not tested in this condition.
- If you have **problems with your kidneys**, please ask your doctor for advice.
If you have moderate kidney problems, your doctor will start Urorec with caution and possibly with a lower dose (see section 3 “Dose”).
If you have severe kidney problems, you should not take Urorec.
- 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.
- 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.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

Children and adolescents

Do not give this medicine to children and adolescents below 18 years since there is no relevant indication for this age group.

Other medicines and Urorec

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** (in particular, medicines called alpha₁-blockers, such as prazosin or doxazosin) as there may be the potential risk that the effect of these medicines is increased whilst taking Urorec.
- **antifungal medicines** (such as ketoconazole or itraconazole), **medicines used for HIV-AIDS** (such as ritonavir) or **medicines used after transplants to prevent organ rejection** (such as cyclosporin) because these medicines can increase the blood concentration of Urorec.
- **medicines used for treating problems in getting or keeping an erection** (such as sildenafil or tadalafil), since the concomitant use with Urorec might lead to a slight decrease in blood pressure.
- **medicines for epilepsy or rifampicin** (a medicine to treat tuberculosis), since the effect of Urorec may be reduced.

Pregnancy and breast-feeding

Urorec is not intended for use by women.

Fertility

Urorec may reduce the amount of sperm, and so could temporarily affect your ability to father a child. If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or operate machines if you feel faint, dizzy, drowsy or have blurred vision.

3. How to take Urorec

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

The recommended dose is one capsule of Urorec 8 mg per day by oral administration.

Take the capsule always with food, preferably at the same time every day. Do not break or chew the capsule, but swallow it whole, preferably with a glass of water.

Patients with kidney problems

If you have moderate kidney problems, your doctor may prescribe a different dose. For this purpose Urorec 4 mg hard capsules are available.

If you take more Urorec than you should

If you have taken more than one capsule, inform your doctor as soon as possible. If you become dizzy or feel weak, tell your doctor straight away.

If you forget to take Urorec

You may take your capsule later the same day if you have forgotten to take it earlier. If it is almost time for the next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Urorec

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.

4. Possible side effects

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

Contact your doctor immediately if you notice any of the following allergic reactions: swelling of the face or throat, difficulty in breathing, feeling faint, itchy skin or hives since the consequences could become serious.

The most common side effect is a decrease in the amount of semen released during sex. This effect disappears after discontinuation of Urorec. Please inform your doctor if you are planning to have children.

Dizziness, including dizziness when standing up, and occasionally **fainting**, may occur.

If you do feel weak or dizzy, make sure you sit or lie down straight away until the symptoms have disappeared. If dizziness when standing up or fainting occurs, please inform your doctor as soon as possible.

Urorec may cause complications during a **cataract surgery** (eye surgery because of cloudiness of the lens, see section “Warnings and precautions”).

It is important that you immediately inform your eye specialist if you are using or have previously used Urorec.

The possible side effects are listed below:

Very common side effects (may affect more than 1 in 10 people)

- Abnormal ejaculation (less or no noticeable semen is released during sex, see section “Warnings and precautions”)

Common side effects (may affect up to 1 in 10 people)

- Dizziness, including dizziness when standing up (see also above, in this section)
- Runny or blocked nose
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people)

- Decreased sexual drive
- Nausea
- Dry mouth
- Difficulties in getting or keeping an erection
- Faster heart rate
- Symptoms of allergic reaction affecting the skin like rash, itching, hives and rash caused by a medicine
- Abnormal results of liver function tests
- Low blood pressure

Rare side effects (may affect up to 1 in 1,000 people)

- Fast or irregular heart beats (called palpitations)
- Fainting/ Loss of consciousness

Very rare side effects (may affect up to 1 in 10,000 people)

- Other allergic reactions with swelling of the face or throat

Not known (frequency cannot be estimated from the available data)

- Floppy pupil during cataract surgery (see also above, in this section)

If you feel that your sexual life is affected, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Urorec

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package in order to protect from light and moisture.

Do not use this medicine if you notice that is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Urorec contains

Urorec 8 mg

The active substance is silodosin. Each capsule contains 8 mg of silodosin.

The other ingredients are pregelatinised maize starch, mannitol (E421), magnesium stearate, sodium laurilsulfate, gelatin, titanium dioxide (E171).

Urorec 4 mg

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

The other ingredients are pregelatinised maize starch, mannitol (E421), magnesium stearate, sodium laurilsulfate, gelatin, titanium dioxide (E171), yellow iron oxide (E172).

What Urorec looks like and contents of the pack

Urorec 8 mg are white, opaque, hard gelatin capsules, size 0 (approximately 21.7 x 7.6 mm).

Urorec 4 mg are yellow, opaque, hard gelatin capsules, size 3 (approximately 15.9 x 5.8 mm).

Urorec is available in packs containing 5, 10, 20, 30, 50, 90, 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Recordati Ireland Ltd.
Raheens East
Ringaskiddy Co. Cork
Ireland

Manufacturer

Recordati Industria Chimica e Farmaceutica S.p.A.
Via Matteo Civitali 1
20148 Milan
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

Recordati Ireland Ltd.
Tél/Tel: + 353 21 4379400

България

PharmaSwiss EOOD
Тел.: + 359 2 895 21 10

Česká republika

Herbacos Recordati s.r.o.
Tel: + 420 466 741 915

Danmark

Recordati Ireland Ltd.
Tlf: + 353 21 4379400

Deutschland

Recordati Pharma GmbH
Tel: + 49 731 70470

Eesti

PharmaSwiss Eesti OÜ
Tel: + 372 6827400

Ελλάδα

Recordati Hellas Pharmaceuticals A.E.
Τηλ: + 30 210-6773822

España

Casen Recordati, S.L.
Tel: + 34 91 659 15 50

France

Laboratoires Bouchara-Recordati
Tél: + 33 1 45 19 10 00

Hrvatska

PharmaSwiss d.o.o.
Tel: +385 1 63 11 833

Ireland

Recordati Ireland Ltd.
Tel: + 353 21 4379400

Ísland

Recordati Ireland Ltd.
Sími: + 353 21 4379400

Italia

Recordati Industria Chimica e Farmaceutica S.p.A.
Tel: + 39 02 487871

Lietuva

PharmaSwiss UAB
Tel: + 370 5 2790762

Luxembourg/Luxemburg

Recordati Ireland Ltd.
Tél/Tel: + 353 21 4379400

Magyarország

Recordati Ireland Ltd.
Tel: + 353 21 4379400

Malta

Focused Pharma Ltd.
Tel: + 356 79426930

Nederland

Recordati Ireland Ltd.
Tel: + 353 21 4379400

Norge

Recordati Ireland Ltd.
Tlf: + 353 21 4379400

Österreich

Haemo Pharma GmbH
Tel: + 43 2689 31160

Polska

Recordati Polska sp. z o.o.
Tel: + 48 22 206 84 50

Portugal

Jaba Recordati, S.A.
Tel: + 351 21 432 95 00

România

Recordati România S.R.L.
Tel: + 40 21 667 17 41

Slovenija

Recordati Ireland Ltd.
Tel: + 353 21 4379400

Slovenská republika

Herbacos Recordati s.r.o.
Tel: + 420 466 741 915

Suomi/Finland

Recordati Ireland Ltd.
Puh/Tel: + 353 21 4379400

Κύπρος

G.C. Papaloizou Ltd.
Τηλ: + 357 22 49 03 05

Sverige

Recordati Ireland Ltd.
Tel: + 353 21 4379400

Latvija

PharmaSwiss UAB
Tel: + 370 5 2790762

United Kingdom

Recordati Pharmaceuticals Ltd.
Tel: + 44 1491 576336

This leaflet was last revised in 06/2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.