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EPAR summary for the public

Urorec

silodosin

This is a summary of the European public assessment report (EPAR) for Urorec. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Urorec.

What is Urorec?

Urorec is a medicine that contains the active substance silodosin. It is available as capsules (4 and 8 mg).

What is Urorec used for?

Urorec is used to treat the symptoms of benign prostatic hyperplasia (BPH, an enlarged prostate gland) in adults. 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.

The medicine can only be obtained with a prescription.

How is Urorec used?

The recommended dose is one 8 mg capsule once a day. For men with moderate kidney problems, the starting dose should be 4 mg once a day. This may be increased to 8 mg once a day after a week. Urorec is not recommended for patients with severe kidney problems.

The capsules should be taken with food, preferably at the same time every day. They should be swallowed whole, preferably with a glass of water.

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How does Urorec work?

The active substance in Urorec, silodosin, is an alpha adrenoreceptor 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.

How has Urorec been studied?

The effects of Urorec were first tested in experimental models before being studied in humans. Urorec has been compared with placebo (a dummy treatment) in three main studies involving over 1,800 men with BPH. One of these studies also compared Urorec with tamsulosin (another medicine used for BPH).

The main measure of effectiveness in all three studies was the improvement of the patients' international prostate symptom score (IPSS) after 12 weeks of treatment. IPSS is a rating of the patient's symptoms such as the inability to empty the bladder, and the urge to urinate repeatedly or to strain while urinating. The patients rated the severity of their symptoms themselves.

What benefit has Urorec shown during the studies?

Urorec was more effective than placebo and as effective as tamsulosin at reducing symptoms of BPH. In the two studies where Urorec was compared only with placebo, the IPSS was around 21 points at the start of the study. After 12 weeks, it had fallen by around 6.4 points in the men who took Urorec, and by around 3.5 points in the men who took placebo. In the third study, IPSS was around 19 points before treatment, falling by 7.0 points in the men who took Urorec after 12 weeks, 6.7 points in the men who took tamsulosin and 4.7 points in the men who took placebo.

What is the risk associated with Urorec?

The most common side effect with Urorec (seen in more than 1 patient in 10) is a reduction in the amount of semen released during ejaculation. Intra operative floppy iris syndrome (IFIS) occurs in some patients taking alpha adrenoreceptor antagonists and may lead to complications during cataract surgery. IFIS is a condition that makes the iris floppy. For the full list of all side effects and restrictions with Urorec, see the package leaflet.

Why has Urorec been approved?

The CHMP decided that Urorec's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Urorec?

A risk management plan has been developed to ensure that Urorec is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Urorec, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes Urorec will ensure that eye surgeons are provided with information on IFIS in all Member States where the medicine will be marketed.

Other information about Urorec

The European Commission granted a marketing authorisation valid throughout the European Union for Urorec on 29 January 2010.

The full EPAR for Urorec can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Urorec, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.