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Silodosin Recordati (*silodosin*)

An overview of Silodosin Recordati and why it is authorised in the EU

What is Silodosin Recordati and what is it used for?

Silodosin Recordati is a medicine 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.

This medicine is identical to Urorec, which has been authorised in the EU since 29 January 2010.

How is Silodosin Recordati used?

Silodosin Recordati can only be obtained with a prescription and is available as capsules (4 and 8 mg). 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. Silodosin Recordati is not recommended for patients with severe kidney problems.

The capsules should be taken with food, preferably at the same time every day. For more information about using Silodosin Recordati, see the package leaflet or contact your doctor or pharmacist.

How does Silodosin Recordati work?

The active substance in Silodosin Recordati, silodosin, is an alpha-adrenoreceptor antagonist. It works by blocking receptors (targets) 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.

What benefits of Silodosin Recordati have been shown in studies?

Three main studies in over 1,800 men showed that Silodosin Recordati was effective at reducing symptoms of BPH, such as problems with urinating.

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The symptoms were measured using the international prostate symptom score (IPSS). In two of the studies the IPSS was around 21 points at the start of the study. After 12 weeks, the IPSS fell by 6.4 points in the men who took Silodosin Recordati compared with 3.5 points in the men who took placebo (a dummy treatment). In the third study, the IPSS was around 19 points before treatment and fell by 7 points with Silodosin Recordati compared with 6.7 points in men who took tamsulosin (another medicine used for BPH) and 4.7 points with placebo.

What are the risks associated with Silodosin Recordati?

The most common side effect with Silodosin Recordati (which may affect more than 1 in 10 people) 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 side effects and restrictions of Silodosin Recordati, see the package leaflet.

Why is Silodosin Recordati authorised in the EU?

Silodosin Recordati is effective at reducing problems with urinating in men with BPH and its side effects are comparable to those seen with other medicines of the same class. The European Medicines Agency therefore decided that Silodosin Recordati's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Silodosin Recordati have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Silodosin Recordati are continuously monitored. Side effects reported with Silodosin Recordati are carefully evaluated and any necessary action taken to protect patients.

Other information about Silodosin Recordati

Silodosin Recordati received a marketing authorisation valid throughout the EU on 7 January 2019.

Further information on Silodosin Recordati can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/silodosin-recordati.

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