15 November 2018
EMA/766073/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Silodosin Recordati

silodosin

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Silodosin Recordati, intended for the treatment of the signs and symptoms of benign prostatic hyperplasia. The applicant for this medicinal product is Recordati Ireland Ltd.

Silodosin Recordati will be available as 4-mg and 8-mg capsules. The active substance of Silodosin Recordati is silodosin, a α1A-adrenoreceptor antagonist (ATC code: G04CA04) that decreases the bladder outlet resistance and improves storage (irritative) and voiding (obstructive) lower urinary tract symptoms.

Silodosin Recordati is a generic of Urorec which has been authorised in the EU since 29 January 2010. Studies have demonstrated the satisfactory quality of Silodosin Recordati. Since Silodosin Recordati is identical to the reference medicinal product, a bioequivalence study versus the reference medicinal product Urorec was not required. A question and answer document on generic medicines can be found here.

The full indication is: "Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult men".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact