European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 November 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
UROREC

International Nonproprietary Name (INN): ***silodosin***

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Urorec 4 mg, 8 mg, hard capsules, intended for treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). The applicant for this medicinal product is Recordati Ireland Ltd.

The active substance of Urorec is silodosin, a urological medicinal product (ATC code G04CA04). Silodosin is a selective α_{1A}-adrenoreceptor antagonist. Blockade of α_{1A}-adrenoreceptors causes smooth muscle in the prostate, bladder base, bladder neck, prostatic capsule and prostatic urethra to relax, thus decreasing bladder outlet resistance.

The benefits with Urorec are its ability to improve lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) including decrease in both storage (irritative) and voiding (obstructive) symptoms of BPH. The most common side effects are transient ejaculatory disorders such as retrograde ejaculation and anejaculation (ejaculatory volume reduced or absent).

A pharmacovigilance plan for Urorec, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)".

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Urorec and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu