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

London, 24 September 2009
Doc.Ref. EMEA/CHMP/440521/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
SILDENAFIL ACTAVIS

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

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Sildenafil Actavis, 25, 50 and 100 mg, Film-coated tablet intended for treatment of erectile dysfunction. The applicant for this medicinal product is Actavis Group PTC ehf.

The active substance of Sildenafil Actavis is sildenafil (as citrate), a drug used in erectile dysfunction (G04BE03). The physiological mechanism responsible for erection of the penis involves the release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. Nitric oxide then activates the guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood.
Sildenafil is a potent and selective inhibitor of phosphodiesterase type 5 (PDE5) in the corpus cavernosum, where PDE5 is responsible for degradation of cGMP. Sildenafil has a peripheral site of action on erections. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum but potently enhances the relaxant effect of NO on this tissue.

Sildenafil Actavis is a generic of Viagra, which has been authorised in the EU since 14 September 1998. Studies have demonstrated the satisfactory quality of Sildenafil Actavis, and its bioequivalence with Viagra. A question-and-answer document on generic medicines can be found here.

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

The approved indication is:

Treatment of men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.
In order for Sildenafil Actavis to be effective, sexual stimulation is required.

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 Sildenafil Actavis 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 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu