20 September 2012
EMA/CHMP/293550/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cialis

tadalafil

On 20 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Cialis. The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication for the 5 mg strength only as follows:
"Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males including those with erectile dysfunction."

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

For information, the full indications for Cialis 5 mg will be as follows[2]:

Treatment of erectile dysfunction in adult males.

In order for tadalafil to be effective **for the treatment of erectile dysfunction**, sexual stimulation is required.

Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

CIALIS is not indicated for use by women.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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