25 September 2014
EMA/CHMP/476904/2014
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Tadalafil Mylan

tadalafil

On 25 September 2014 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tadalafil Mylan, 2.5 mg, 5 mg, 10 mg and 20 mg film-coated tablet intended:

For 2.5 mg, 10 mg and 20 mg:

- Treatment of erectile dysfunction in adult males.

  In order for tadalafil to be effective, sexual stimulation is required.

Tadalafil Mylan is not indicated for use by women.

For 5 mg:

- 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.

Tadalafil Mylan is not indicated for use by women.

The applicant for this medicinal product is Generics (UK) Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Tadalafil Mylan is tadalafil, a urological, drug used in erectile dysfunction (G04BE08). It is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the treatment of erectile dysfunction in the absence of sexual

[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 4HB ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

stimulation.

Tadalafil Mylan is a generic of Cialis, which has been authorised in the EU since 12 November 2002. Studies have demonstrated the satisfactory quality of Tadalafil Mylan, and its bioequivalence with the reference product Cialis. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Tadalafil Mylan will be implemented as part of the marketing authorisation.

The approved indication is:

For 2.5 mg, 10 mg and 20 mg: “Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required. Tadalafil Mylan is not indicated for use by women.”

For 5 mg: “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. Tadalafil Mylan is not indicated for use by women.”

It is proposed that Tadalafil Mylan is prescribed by physicians experienced in the treatment of erectile dysfunction in adult males, and treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

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 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 there to be a favourable benefit to risk balance for Tadalafil Mylan and therefore recommends the granting of the marketing authorisation.