26 January 2017
EMA/CHMP/38153/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tadalafil Lilly

tadalafil

On 26 January 2017, 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 Lilly, for the treatment of erectile dysfunction and treatment of the signs and symptoms of benign prostatic hyperplasia. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Tadalafil Lilly will be available as film-coated tablets (2.5, 5, 10 and 20 mg). The active substance of Tadalafil Lilly is tadalafil, a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5) (ATC code: G04BE08).

As a treatment for erectile dysfunction, 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. This effect is also observed in the smooth muscle of the prostate, the bladder and their vascular supply. The resulting vascular relaxation increases blood perfusion which may be the mechanism by which symptoms of benign prostatic hyperplasia are reduced.

The application for Tadalafil Lilly was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Tadalafil Lilly is Cialis.

The full indication for Tadalafil Lilly 2.5 mg, 10 mg and 20 mg tablets is:

> “Treatment of erectile dysfunction in adult males.
>
> In order for tadalafil to be effective, sexual stimulation is required.
>
> Tadalafil Lilly is not indicated for use by women”.

The full indication for the 5 mg tablets is:

> “Treatment of erectile dysfunction in adult males.

[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

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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 Lilly is not indicated for use by women".

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.