



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2013
EMA/CHMP/61591/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Spedra avanafil

On 25 April 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Spedra, 50 mg, 100 mg, 200 mg, tablet intended for the treatment of erectile dysfunction in adult men. The applicant for this medicinal product is VIVUS BV. 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 Spedra is avanafil, a selective phosphodiesterase (PDE) type 5 inhibitor that leads to higher cyclic guanosine monophosphate (cGMP)-specific PDE5 levels. This enhances smooth muscle relaxation, which results in an inflow of blood into the penile tissues, thereby producing an erection.

The benefit with Spedra is its effect on the ability of men with erectile dysfunction to achieve and maintain an erection sufficient for satisfactory sexual activity. It was observed in clinical trials that Spedra increased the percentage of sexual attempts resulting in successful intercourse by roughly 20-30% over placebo in the general population of adult men with erectile dysfunction. The most common side effects are headache, flushing, nasal and sinus congestion, dyspepsia and back pain.

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

The approved indication is: "Treatment of erectile dysfunction in adult men. In order for Spedra to be effective, sexual stimulation is required."

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.

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.



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