EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/382383/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Senstend

lidocaine / prilocaine

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Senstend, intended for the treatment of premature ejaculation in adult men. The applicant for this medicinal product is Plethora Pharma Solutions Limited.

Senstend will be available as a cutaneous spray solution (150 / 50 mg/ml). The active substances of Senstend are lidocaine and prilocaine, local anaesthetics (ATC code: N01BB20) that act by blocking the transmission of nerve impulses in the head (glans) of the penis. This action reduces stimulation and helps delay ejaculation time and allow satisfactory sexual activity.

The benefits with Senstend are its ability to provide improvements in ejaculatory control and sexual satisfaction and a reduction in distress related to ejaculation. The most common side effects in men using Senstend are hypoaesthesia (lack of sensation) and erectile dysfunction, while the most common side effects in their female sexual partners are hypoaesthesia and a burning sensation in the genital area.

The application for Senstend 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 Senstend is Fortacin.

The full indication is: “treatment of primary premature ejaculation in adult men”.

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

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