



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/488493/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Lidocaine/Prilocaine Plethora

lidocaine/prilocaine

On 19 September 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 Lidocaine/Prilocaine Plethora, 150 mg/ml + 50 mg/ml, cutaneous spray, solution, intended for the treatment of primary premature ejaculation in adult men. The applicant for this medicinal product is Plethora Solutions Ltd. 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 substances of Lidocaine/Prilocaine Plethora are lidocaine and prilocaine, local anaesthetics that act by blocking the transmission of nerve impulses in the head (glans) of the penis. This reduces stimulation and helps delay ejaculation time and allow satisfactory sexual activity. The medicine will be available as a cutaneous spray solution containing 150 mg of lidocaine and 50 mg prilocaine per ml. It will only be obtained with a doctor's prescription.

The CHMP decided that the benefits of the medicine were greater than its risks after assessing data on quality, safety and efficacy, including clinical trials where Lidocaine/Prilocaine Plethora was compared with placebo (a dummy treatment) in the general population of adult men with premature ejaculation. Lidocaine/Prilocaine Plethora was shown to provide an improvement in ejaculatory control during sexual intercourse, sexual satisfaction and reduction in distress related to ejaculation, and to increase the time to ejaculation (intravaginal ejaculatory latency time) from 0.58 to 3.17 minutes, and from 0.56 to 0.94 minutes in the placebo group. The most common side effects in both men and women were hypoesthesia (lack of sensation) and genital burning sensation, and in men erectile dysfunction and for female sexual partners headache, influenza, nasopharyngitis and vulvovaginal discomfort.

A pharmacovigilance plan for Lidocaine/Prilocaine Plethora will be implemented as part of the marketing authorisation.

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

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.



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.