19 September 2019
EMA/625405/2019
Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Senstend

International non-proprietary name: lidocaine / prilocaine

Procedure No. EMEA/H/C/005298/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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List of abbreviations

CHMP	Committee for Medicinal Products for Human Use
EMA	European Medicines Agency
EURD	Union Reference Date
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
RMP	Risk Management Plan
PSUR	Periodic Safety Update Report

1. Background information on the procedure

1.1. Submission of the dossier

The applicant Plethora Pharma Solution Limited submitted on 3 May 2019 an application for Marketing Authorisation (MA) to the European Medicines Agency (EMA) for Senstend, through the centralised procedure. The eligibility to the centralised procedure was agreed upon by the EMA/CHMP on 31 January 2019.

The applicant applied for the following indication:

Senstend is indicated for the treatment of primary premature ejaculation in adult men.

The legal basis for this application refers to:

Article 10(c) of Directive 2001/83/EC – relating to informed consent from a marketing authorisation holder for an authorised medicinal product.

The application submitted is composed of administrative information with a letter from a MAH Recordati Ireland Ltd allowing the cross reference to relevant quality, non-clinical and/or clinical data.

Information on Paediatric requirements

Not applicable

Information relating to orphan market exclusivity

Similarity

Not applicable

Scientific advice

The applicant did not seek scientific advice at the CHMP.

1.2. Manufacturers

Manufacturer responsible for batch release

Pharmaserve (North West) Limited
9 Arkwright Rd, Astmoor Industrial Estate
Runcorn WA7 1NU
United Kingdom

Recordati Industria Chimica e Farmaceutica S.p.A
Via Matteo Civitali 1
Milan 20148
Italy

1.3. Steps taken for the assessment of the product

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Maria Concepcion Prieto Yerro Co-Rapporteur: Johann Lodewijk Hillege

The application was received by the EMA on	3 May 2019
The procedure started on	27 May 2019
The Rapporteur's first Assessment Report was circulated to all CHMP members on	02 July 2019
The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on	01 July 2019
The PRAC agreed on the PRAC Assessment Overview and Advice to CHMP during the meeting on	11 July 2019
The Rapporteur circulated the updated CHMP Assessment Report on	18 July 2019
The CHMP agreed on the consolidated List of Questions to be sent to the applicant during the meeting on	25 July 2019
The applicant submitted the responses to the CHMP consolidated List of Questions on	20 August 2019
The Rapporteur circulated the Joint Assessment Report on	04 September 2019
The Rapporteur circulated the updated Joint Assessment Report on	12 September 2019
The CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a marketing authorisation to Senstend on	19 September 2019

2. Scientific discussion

2.1. Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC as amended.

Accordingly, the MAH of the reference product, Fortacin has provided consent to allow access to Module 2 to Module 5 of the initial dossier and any subsequent post-marketing procedures submitted, assessed and approved. The complete assessment history of Fortacin is available on the EMA website. The application for Senstend consists only of Module 1 information.

The proposed indication for Senstend is the same as the approved indication for the reference product.

This application is for the following presentations:

- Senstend 150 mg/ml, 50 mg/ml cutaneous spray, solution

2.2. Quality aspects

Since this application is an informed consent of the Fortacin application, the quality data in support of the Senstend application are identical to the up-to-date quality data of the Fortacin dossier, which has been assessed and approved (including all post-marketing procedures).

2.3. Non-clinical aspects

Since this application is an informed consent of the Fortacin application, the non-clinical data in support of the Senstend application are identical to the up-to-date non-clinical data of the Fortacin dossier, which has been assessed and approved (including all post-marketing procedures).

2.4. Ecotoxicity/environmental risk assessment

Since this application is an informed consent application, the medicinal product subject to this application is intended to be administered at comparable dose levels and for indications that were already approved in the Union for Fortacin. Based on the assumption that Senstend cutaneous spray, solution is intended to substitute for identical products on the market and it is unlikely to result in any significant increase in combined sales volumes, the approval of the product does not result in an increase of the total quantity of the active ingredients released into the environment. This justification is considered acceptable and in accordance with the Guideline on the environmental risk assessment of medicinal products for human uses (EMEA/CHMP/SWP/4447/00).

2.5. Clinical aspects

Since this application is an informed consent of the Fortacin application, the clinical data in support of the Senstend application are identical to the up-to-date clinical data of the Fortacin dossier, which have been assessed and approved (including all post-marketing procedures). No additional clinical studies have been submitted.

2.6. Risk Management Plan

The submitted Risk Management Plan (RMP) of Senstend (version 0.1) is in line with the current approved version of the RMP (version 3.0) for Fortacin. The safety concerns, the pharmacovigilance plan and the risk minimisations measures are identical.

However, after approval, the RMP should be updated in line with the Good Pharmacovigilance Practices (GVP) Module V version 2.

The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

2.7. Pharmacovigilance

Pharmacovigilance system

The CHMP considered that the pharmacovigilance system summary as described by the applicant fulfils the requirements of Article 8(3) of Directive 2001/83/EC.

Periodic Safety Update Reports submission requirements

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

2.8. Product information

2.8.1. User consultation

A justification for not performing a full user consultation with target patient groups on the package leaflet has been submitted by the applicant and has been found acceptable for the following reasons:

The Patient Information Leaflet for the reference product, Fortacin, was the subject of a user testing study, which was completed successfully.

As the Patient Information Leaflet for Senstend is identical (with the exception of the product name) to that of the reference product, the user testing of the Patient Information Leaflet for the reference product can be taken to apply equally to Senstend.

2.8.2. Braille

The name of the medicinal product followed by its strength is expressed in Braille format is included in the proposed labelling and mock-ups for the cartons of the product as presented below:

Senstend 150 mg/ml + 50 mg/ml cutaneous spray, solution.

3. Recommendations

Outcome

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers by consensus that the benefit-risk balance of Senstend is favourable in the following indication:

Senstend is indicated for the treatment of primary premature ejaculation in adult men.

The CHMP therefore recommends the granting of the marketing authorisation subject to the following conditions:

Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Other conditions and requirements of the marketing authorisation

Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

Conditions or restrictions with regard to the safe and effective use of the medicinal product

Risk Management Plan (RMP)

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the Member States

Not applicable.