LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Oxaliplatin Eugia
(oxaliplatin)

SE/H/2172/01/DC

This module reflects the scientific discussion for the approval of Oxaliplatin Eugia. The procedure was finalised on 2022-11-09. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Oxaliplatin Eugia, 5 mg/ml, concentrate for solution for infusion.

The active substance is oxaliplatin. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Oxaliplatin Eugia, 5 mg/ml, concentrate for solution for infusion, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Eugia Pharma (Malta) Limited, 5 mg/ml, concentrate for solution for infusion, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and BE, DE, ES, FR, IT, PL and PT as concerned member states (CMS). The application was withdrawn in CZ during clock stop.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Eloxatin, 5 mg/ml, concentrate for solution for infusion, authorised in SE since 2005, with sanofi-aventis AB as marketing authorisation holder.

European Reference Product (ERP)
A European Reference Product is used in CMS PL: Eloxatin, 5 mg/ml, concentrate for solution for infusion, authorised in SE since 2005, with Sanofi-Aventis AB as marketing authorisation holder.
Another European Reference Product was used in CMS CZ (until the withdrawal in CZ): Eloxatine, 5 mg/ml, concentrate for solution for infusion, authorised in FR since 2004 with Sanofi-Aventis France as marketing authorisation holder.
The justification to use these products is based on RMS's own files and information received from FR, respectively.

Potential similarity with orphan medicinal products
According to the application form and a check of the Community Register of orphan medicinal products there is no medicinal product designated as an orphan medicinal product for a condition relating to the indication proposed in this application.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

Pharmacology/Pharmacokinetics/Toxicology
Pharmacodynamic, pharmacokinetic and toxicological properties of oxaliplatin are well known. As oxaliplatin is a widely used, well-known active substance, no further studies are required and the applicant provides none. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
Since Oxaliplatin Eugia is a generic product, it will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Oxaliplatin Eugia from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics
The applied product is to be administered as an intravenous solution containing the same active substance in the same concentration as the reference product. The applied product also contains the same excipients in similar amounts as the reference product. For this type of product, no bioequivalence studies are required according to the Guideline on the investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1).

Pharmacodynamics/Clinical efficacy/Clinical safety
No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. As bioequivalence with the originator product can be assumed (see above), additional data is not necessary.

During the procedure, the SmPC and PL was updated with texts according to the PRAC recommendation from PSUSA/00002229/202104.

Risk Management Plan
The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to oxaliplatin.

Safety specification
In accordance with section V.C.1.1 of the Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk management systems (EMA/838713/2011 Rev 2), modules SI to SVII of the RMP have been omitted.

Table SVIII.1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

Pharmacovigilance Plan
Routine pharmacovigilance is suggested, and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures
Routine risk minimisation is suggested, and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP
The submitted Risk Management Plan, version 1.0 signed 13th July, 2021, is considered acceptable.

An updated RMP should be submitted:
- At the request of the RMS;
- 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.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

A user consultation with target patient groups on the package information leaflet (PL) has been performed on the basis of a bridging report making reference to NL/H/820/01/DC, Oxalisin, 5 mg/ml, concentrate for solution for infusion, Pharmachemie B.V., the Netherlands and NL/H/3750/01/DC, Mebeverine HCl Aurobindo, 200 mg, modified-release capsules, hard.

Assessment of the Bridging proposed by the applicant was circulated by the RMS in an addendum to the Day 70 AR dated 2021-11-26.

The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Oxaliplatin Eugia, is found adequate. There are no objections to approval of Oxaliplatin Eugia, from non-clinical nor clinical point of view. The product information is acceptable. The benefit/risk ratio is considered positive and Oxaliplatin Eugia is recommended for approval.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The decentralised procedure for Oxaliplatin Eugia, 5 mg/ml, concentrate for solution for infusion, was positively finalised on 2022-11-09.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
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