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Public Assessment Report

Scientific discussion

Redenac 0.9 mg/ml eye drops, solution

(Bromfenac sodium sesquihydrate)

ES/H/0957/001/DC

Date of this report:	15/10/2025

This module reflects the scientific discussion for the approval of Redenac 0.9 mg/ml eye drops, solution. The procedure was finalised on 15 October 2025. For information on changes after this date please refer to the module 'Update'.

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I INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have agreed to grant a marketing authorisation for Redenac 0.9 mg/ml eye drops solution.
The product is indicated for*:* Treatment of postoperative ocular inflammation following cataract extraction.

A comprehensive description of the indications and posology is given in the SmPC.

II EXECUTIVE SUMMARY

II.1 Rationale for the product

II.2 About the product

Bromfenac is included in the Pharmacotherapeuic group: Ophtalmologicals, Antiinflammatory agents, non-steroids, ATC code: S01BC11.

Bromfenac is a NSAID with anti-inflammatory and analgesic activities. Ocular actions of prostaglandins are manifested in three ways: i) by acting on IOP. Prostaglandin E1 (PGE1) and prostaglandin E2 (PGE2) increase the IOP by local vasodilation and increased permeability of the blood–aqueous barrier. Conversely, prostaglandin F2-α (PGF2-α) lowers the IOP which is attributed to increased uveoscleral outflow; ii) by acting on iris smooth muscle to cause miosis; iii) by causing vasodilation and increasing the vascular permeability, thus resulting in increased aqueous humour protein concentration. The anti-inflammatory activity of bromfenac is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase (COX), an important group of enzymes that are active in the inflammatory process.

Drug concentration required to reduce human COX-2 activity to half maximal (IC_{50}) is achieved after a single dose of bromfenac 0.01%. After the instillation of one drop of bromfenac 12 hours prior to surgery, the concentration of bromfenac 0.09% in the aqueous humour of patients undergoing cataract surgery was in excess of the IC_{50} value for COX-2, but not the IC_{50} value for COX-1.

Bromfenac eye drops solution is indicated in adults for the treatment of postoperative ocular inflammation following cataract extraction.

Recommendation for use and posology

Posology
Use in adults, including the elderly
The dose is one drop of [Product name] in the affected eye(s) twice daily, beginning 24 hours after cataract surgery and continuing through the first 2 weeks of the postoperative period.

The treatment should not exceed 2 weeks as safety data beyond this is not available.

Renal and Hepatic impairment
No dosage adjustment is necessary in patients with impaired kidney function, but clinical monitoring appropriate for their individual condition is recommended.

Hepatic impairment has been argued to alter oral bromfenac disposition, particularly in patients with PT >13.5 sec or bilirubin >1.3 mg/dl. In these patients, the clearance of bromfenac was reported to be reduced by 40%, thus potentially leading to accumulation after multiple doses. However, clinical studies on topical bromfenac have not been carried out.

Paediatric population

No pharmacokinetic studies have been carried out regarding the effect of bromfenac in the paediatric population.

Method of administration
For ocular use.

If more than one topical ophthalmic medicinal product is being used, each one should be administered at least 5 minutes apart.

To prevent contamination of the dropper-tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper-tip of the bottle.

II.3 General comments on the submitted dossier

This is a decentralised application for Redenac 0.9 mg/ml eye drops, solution in accordance with article 10.3 of the Directive 2001/83/EC, hybrid application. The originator product is Yellox 0.9 mg/ml eye drop solution by Bausch Lomb Ireland Limited registered since 18 May 2011 (EU/1/11/692/001).

With Spain as the Reference Member State in this Decentralized Procedure, Bruschettini S.r.l. is applying for the Marketing Authorisations for Redenac in Italy and Spain.

European Reference Product (ERP)

N/A

Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity. Potential similarity with orphan medicinal products.

N/A

Derogation(s) from market exclusivity

N/A

II.4 General comments on compliance with GMP, GLP, GCP and agreed ethical principles

GMP
The RMS has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product.

GMP active substance
Regarding the statement on GMP for the active substance a suitable declaration is provided from the QP of the manufacturer responsible for manufacture of the finished product and batch release situated in the EU.

III SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 Quality aspects

Drug substance
The drug substance is bromfenac (in the form of bromfenac sodium sesquihydrate). The ASMF procedure is used and separate assessment report on the ASMF are provided. All issues raised on the content of the ASMF have been suitably addressed and the ASMF can then be considered acceptable.

The control tests and specifications for drug substance product are adequately drawn up.

Stability studies with the drug substance have been performed by the ASMF holder. No significant changes in any parameters were observed. The proposed retest period of 60 months is justified.

Drug Product
Redenac 0.9 mg/ml eye drops is a sterile formulation packed in a 5 mL multidose sterile low-density polyethylene (LDPE) bottle.

The development of the product has been described, the choice of excipients is justified and their functions explained.

The product specifications cover appropriate parameters for this dosage form. Validations of the analytical methods have been presented. Sufficient drug product batch analytical data have been provided. The batch analysis results show that the finished products meet the specifications proposed.

The conditions used in the stability studies are according to the ICH stability guideline. The control tests and specifications for drug product are adequately drawn up.

The proposed shelf-life of 24 months with the special storage condition "Do not store above the 25°C" for the drug product is considered acceptable.

III.2 Non clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of bromfenac are well known. As bromfenac is a widely used, well-known active substance, the Applicant has not provided additional studies and further studies are not required.

Environmental Risk Assessment (ERA)

Bromfenac PEC surface water value is below the action limit of 0.01 µg/L and is not a PBT substance as log Kow does not exceed 4.5. No risks to the environment are to be expected when the medicinal product is used as recommended in the SmPC.

III.3 Clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of bromfenac are well known. As bromfenac is a widely used, well-known active substance, the applicant has not provided additional studies, and further studies are not required. Overview based on literature review is, thus, appropriate. The PI documents has been amended according to the RMS and CMSs comments, and it is fully aligned with the reference product and the guidelines of application.

Pharmacokinetics

The application does contain an adequate review of published clinical data.

Based on the principles outlined in the *Guideline on quality and equivalence of locally applied, locally acting cutaneous products, EMA/CHMP/QWP/708282/2018, adopted 9 September 2024,* the test product, Redenac 0.9 mg/mL eye drops solution, and the reference product, Yellow 0.9 mg/mL eye drops solution, are both aqueous solutions with essentially similar qualitative and quantitative composition. They are also presented in the same pharmaceutical form (eye drops solution). Considering the similarity in formulation and physicochemical characteristics, the requirement to conduct additional studies to demonstrate therapeutic equivalence is not deemed necessary.

Pharmacodynamics

No new studies on pharmacodynamics have been submitted, which is acceptable for this hybrid application.

Clinical efficacy

No new studies on pharmacodynamics have been submitted, which is acceptable for this hybrid application.

Clinical safety

No new studies on pharmacodynamics have been submitted, which is acceptable for this hybrid application.

Summary Pharmacovigilance system

The Applicant has submitted a signed Summary of the Applicant's and/or Proposed Future MAH's* Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

* applicable in case the future MAH in RMS/CMSs will be different from the applicant

Risk Management Plan
The MAH has submitted a risk management plan (version 0.2, 19 January 2025), 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 Redenac 0.9 mg/ml eye drops, solution.

There are neither proposed additional pharmacovigilance activities nor proposed additional risk minimisation measures planned for Redenac 0.9 mg/ml eye drops, solution.

IV BENEFIT RISK ASSESSMENT

From a clinical perspective, approval of the test product is recommended.

V RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

V.1 List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

Description	Due date

V.2 List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

- **<Additional risk minimisation measures (including educational material)>**

The educational material should contain the following key elements:

- ○

- **<Obligation to conduct post-authorisation measures in accordance with Article 21a of Directive 2001/83>**

The MAH shall complete, within the stated timeframe, the below measures:

Description	Due date

- **<Specific obligation to complete post-authorisation measures for <the marketing authorisation under exceptional circumstances in accordance with Article 22 of Directive 2001/83/EC>**

<This being a marketing authorisation under exceptional circumstances and pursuant to Article 22 of Directive 2001/83/EC, the MAH shall complete, within the stated timeframe, the following measures:>

Description	Due date

V.3 Summary of Product Characteristics (SmPC)

The approved SmPC is available in the MRI Product Index.

V.4 Package Leaflet (PL)

V.4.1 Package Leaflet

The approved PL is available in the MRI Product Index.

V.4.2 Assessment of User Testing

The results of the user consultation with target patient groups on the package leaflet submitted by the applicant show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

The test consisted of a pilot test with 4 participants, followed by two rounds with 10 participants each. The questions covered the following areas sufficiently: traceability, comprehensibility and applicability.

V.5 Labelling

The approved Labelling is available in the MRI Product Index.

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
-	-	-	-	-	-