LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Bimabloc
(bimatoprost, timolol maleate)

SE/H/2400/001/DC

This module reflects the scientific discussion for the approval of Bimabloc. The procedure was finalised on 2024-11-20. 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 Bimabloc, 0,3 mg/ml + 5 mg/ml, eye drops, solution.

The active substance is bimatoprost, timolol maleate, timolol. 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 Bimabloc, 0.3 mg/ml + 5 mg/ml, eye drops, solution, is a hybrid Art. 10(3) application submitted according to Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and NL and NO as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is GANFORT, 0.3 mg/ml + 5 mg/ml, eye drops, solution, authorised in EU since 2006, with AbbVie Deutschland GmbH & Co. KG as marketing authorisation holder.

Potential similarity with orphan medicinal products
N/A

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 bimatoprost and timolol are well known. As bimatoprost and timolol are widely used, well-known active substances, no further studies are required, nor does the applicant provide any. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
A justification for absence of environmental risk assessment has been submitted.

The medicinal product Bimatoprost + Timolol (0.3 mg/ml + 5 mg/ml) is essentially similar to the reference product "GANFORT® 0.3 mg/ml+ 0.5 mg/ml eye drops, solution" which is marketed by Allergan Pharmaceuticals in Europe since 2006, including Sweden, Norway and The Netherlands (countries of the current DCP). Therefore, this drug product does not represent the release of a new chemical entity to the environment. The introduction of this product in the market will not impact the overall current size of the market or market trends. Bimatoprost + Timolol (0.3 mg/ml+ 5 mg/ml), Eye Drops Solution will just replace sales of the originator product in the European market. Accordingly, the use of this product will not lead to an increase of the treated population and no additional risks are to be expected. The justification is considered acceptable.

From a non-clinical perspective, approval can be recommended.

IV. CLINICAL ASPECTS

Pharmacodynamics and clinical aspects
No new studies on pharmacokinetics, pharmacodynamics, clinical efficacy or clinical safety have been submitted. Provided that similarity with the originator product is demonstrated by means of *in vitro* data, clinical data is not necessary.

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 Bimabloc.

Part II Safety specification

Summary of safety concerns	
Important identified risks	Iris hyperpigmentation
	Punctate keratitis
	Acute asthma and asthmatic symptoms
	Bradycardia
	Cystoid macular edema
Important potential risks	Choroidal detachment
	Cardiovascular events (angina, hypotension, congestive heart failure)
Missing information	Exposure in paediatric patients
	Exposure in pregnancy and lactation

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

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

Part VI Summary of the RMP
The Summary of the RMP is endorsed.

Conclusion RMP assessment
The summary of safety concerns is aligned with the reference product. For an abridged application this is acceptable and therefore the submitted Risk Management Plan, version 1 signed 09-Oct-2023 is considered acceptable.

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 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

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was English.
The results 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.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

There are no objections to approval of Bimabloc, from a non-clinical and clinical point of view. The quality of the generic product, Bimabloc, is found adequate. Active substances and excipients of the proposed and reference product are qualitatively and quantitatively essentially similar, i.e., the criteria for a biowaiver are met and no new clinical data is necessary. The product information is acceptable. The benefit/risk ratio is considered positive, and the application is therefore recommended for approval. No need for conditions under Article 21a/22 of Directive 2001/83 has been identified.

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

Post approval commitments
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 Bimabloc, 0,3 mg/ml + 5 mg/ml, eye drops, solution was positively finalised on 2024-11-20.

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

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
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