IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Opticrom allergy 2% w/v eye drops, from Sanofi-aventis Ireland limited on 6th of May 2011 indicated for :

the relief and treatment of allergic conjunctivitis and vernal keratoconjunctivitis (vernal or spring catarrh).

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as an 'informed consent' application. This means that the Marketing Authorisation Holder for Opticrom 2% w/v eye drops PA 540/116/1 , an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Opticrom allergy 2% w/v eye drops. Opticrom allergy 2% w/v eye drops has the same qualitative and quantitative composition in terms of active substance and the same pharmaceutical form as Opticrom 2% w/v eye drops. This is a national application submitted to the Irish Medicines Board.

The Summary of Product Characteristics for (SPC) for this medicinal product is available on the IMB's website at www.imb.ie

Name of the product	Opticrom Allergy 2% w/v Eye Drops, Solution
Name(s) of the active substance(s) (INN)	SODIUM CROMOGLICATE
Pharmacotherapeutic classification (ATC code)	S01GX01
Pharmaceutical form and strength(s)	2% w/v Eye Drops, Solution
Marketing Authorisation Number(s) in Ireland (PA)	PA540/116/2
Marketing Authorisation Holder	Sanofi-aventis Ireland Limited

II. QUALITY ASPECTS

II.1. Introduction

This application is for Opticrom Allergy 2% w/v eye drops.

II.2-3
Since this application is an informed consent of Opticrom 2% w/v eye drops Sanofi-aventis Ireland limited application, the Quality date in support of this product is identical to the up-to-date Quality data of the Opticrom 2% w/v eye drops dossier wich has been assessed and approved. A more detailed Quality comment is not required.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Opticrom allergy 2%w/v eye drops.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Opticrom 2% w/v Eye drops, solution PA 540/116/1 on the European market and therefore no new preclinical data is required. This is acceptable for this type of application.

III.2 Toxicology

Animal studies have shown that sodium cromoglicate has a very low order of local or systemic toxicity.

III.3 Ecotoxicity/environmental risk assessment

Not applicable.

III.4 Discussion on the non-clinical aspects

Additional non clinical tests are not warranted as this application is an informed consent application.

IV. CLINICAL ASPECTS

IV.1 Introduction

Sodium Cromoglicate 2.0% w/v. is a well known active substance with established efficacy and tolerability.
The content of the SPC approved during the national/ procedure is in accordance with that accepted for the reference product Opticrom Allergy 2%w/v Eye Drops, solution marketed by Sanofi-Aventis.

No bioequivalence studies have been conducted, this is acceptable as this application is an informed consent application.

IV.2 Pharmacokinetics

Following topical ophthalmic administration of sodium cromoglicate to normal rabbit eyes, less than 0.07% of the dose is absorbed into the systemic circulation.
Similarly, in normal volunteers, analysis of urinary excretion of the drug indicates that only a very small proportion of the dose will drain into the nasal cavity and eventually into the gastrointestinal tract from where absorption is also low. The drug has a high systemic clearance (plasma clearance 7.9 ± 0.9ml $min^{-1}kg^{-1}$), so that any absorbed drug is rapidly cleared from the circulation and accumulation does not occur. Studies in the rabbit indicate that the drug does not accumulate in the eye. Sodium cromoglicate is reversibly bound to plasma proteins (≈65%) and is not metabolised, being excreted unchanged in the bile and urine in approximately equal proportions.

IV.3 Pharmacodynamics

In vitro and *in vivo* animal studies have shown that sodium cromoglicate inhibits the degranulation of sensitised mast cells, which occurs after exposure to specific antigens. Sodium cromglycate acts by inhibiting the release of histamine and various membrane derived mediators of inflammation from mast cells.
Sodium cromoglicate has no intrinsic vasoconstrictor or antihistaminic activity.

IV.4 Clinical Efficacy

Clinical efficacy is assured as this application is the same as Opticrom Allergy 2%w/v Eye Drops, solution.marketed by Sanofi-AventisPA 540/116/1.

IV.5 Clinical Safety

Clinical safety is assured as this application is the same as Opticrom Allergy 2%w/v Eye Drops, solution.marketed by Sanofi-AventisPA 540/116/1

A risk management plan is unnecessary.

The schedule for Periodic Safety Update Reports (PSUR) submission should be on a 3 yearly basis.

The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.

V. OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Opticrom allergy 2% w/v eye drops is the same as Opticrom 2% w/v eye drops PA 540/116/1.
Opticrom 2% w/v eye drops (containing Sodium Cromoglicate 2.0% w/v) is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The IMB, on the basis of the data submitted considered that Opticrom allergy 2% w/v eye drops was the same as the reference product and therefore granted a marketing authorisation.

IMB have granted indefinite validity with 3 yearly PSUR review.

VI. REVISION DATE

October 2021

VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
MA transfer	CRN00C5Z8	SmPC section 7, 8, 10 Package Leaflet **New MA Holder:** Opella Healthcare France SAS T/A Sanofi **New PA number:** PA23180/010/002	N/A	29/10/2021