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RESEARCH**

APPLICATION NUMBER:

206276Orig1s000

SUMMARY REVIEW

NDA 206276

PAZEO (olopatadine hydrochloride ophthalmic solution) 0.7%

Proposed Indication: Ocular Itching Associated With Allergic Conjunctivitis

Summary Review for Regulatory Action

Date	See electronic stamp date
From	Renata Albrecht, MD Division of Transplant and Ophthalmology Products
Subject	Division Director Summary Review
NDA Number	NDA 206276
Related IND	IND 60991
Applicant Name	Alcon Research Ltd.
Date of Submission	July 30, 2014
Date of Receipt	July 30, 2014
Review Type	Priority (includes pediatric data)
PDUFA Goal Date	January 30, 2015
Proprietary Name / Established (USAN) Name	PAZEO Olopatadine hydrochloride ophthalmic solution, 0.7%
Drug Class	Relatively selective histamine H1 antagonist, inhibitor of histamine release from mast cells
Formulation	Ophthalmic solution
Presentation	<ul style="list-style-type: none">• 2.5 mL fill volume in 4 mL bottle
Use	One drop in each affected eye once daily
Proposed Indication	Treatment of ocular itching associated with allergic conjunctivitis
Action for Application	<i>Approval</i>

NDA 206276

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Proposed Indication: Ocular Itching Associated With Allergic Conjunctivitis

Material Reviewed/Consulted OAP Action Package, including:	Names of discipline reviewers
Medical Officer Review	Wiley Chambers 9/15/2014, 12/14/2014
CDTL Review	Bill Boyd 1/29/2015
Statistical Review	Yunfan Deng, Yan Wang 1/2/2015
Pharmacology/Toxicology Review	Aaron Ruhland, Lori Kotch 12/31/2014
Clinical Pharmacology Review	Gerlie Gieser, Philip Colangelo 10/16/2014
OPQ	Libaniel Rodriguez, Balajee Shanmugam, Rapti Madurawe 12/22/2014
Quality Microbiology Review	Stephen Langille, Bryan Riley 1/5/2015
Biopharmaceutics Review, OPQ	Banu Zolnik, Elsbeth Chikhale 12/23/2014
OC/Facilities Inspection	Acceptable (CMC review)
OSI/DGCPC	Roy Blay 12/11/2014, 1/7/2015
OSE/DMEPA Proprietary Name Letter	Rachna Kapoor 12/9/2014 Karen Townsend 12/10/2014
OSE/DMEPA Labeling Review	Rachna Kapoor, Yelena Maslov 11/19/2014
OPDP/DPDP (formerly DDMAC)	Christine Corser 1/6/2015
Pediatric Review Committee	George Greeley 12/05/2014
Pediatric Exclusivity	Matt Bacho 12/16/2014
Project Manager	Lois Almoza

OND=Office of New Drugs,

CDTL=Cross-Discipline Team Leader

OPQ = Office of Product Quality

OSI/DGCPC=Office of Scientific Investigations/Division of Good Clinical Practice Compliance (formerly Division of Scientific Investigation (DSI))

OSE= Office of Surveillance and Epidemiology

DMEPA=Division of Medication Error Prevention and Analysis

OPDP/DPDP=Office of Prescription Drug Promotion/Division of Professional Drug Promotion; formerly, DDMAC=Division of Drug Marketing, Advertising and Communication

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1. Summary and Recommendations

Pazeo (olopatadine hydrochloride ophthalmic solution) 0.7% is a histamine (H1) receptor antagonist that inhibits the mast cells from releasing histamine. It is proposed for the treatment of ocular itching associated with allergic conjunctivitis.

The Indications and Usage section, and the Dosage and Administration section of labeling will provide the following information:

1 INDICATIONS AND USAGE

PAZEO (olopatadine hydrochloride ophthalmic solution) 0.7% is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

2 DOSAGE AND ADMINISTRATION

The recommended dosage of PAZEO is to instill one drop in each affected eye once a day.

All disciplines recommend approval. Product labeling, including carton and container labels have been finalized. The proprietary name PAZEO was found acceptable by DMEPA. OSI recommended that data are reliable. The Office of Compliance recommended the manufacturing facilities are acceptable.

1.1 Deficiencies

None, the application will be approved.

1.2 Post-Marketing Studies:

None

1.3 Other Issues

None

2. Background

Allergic conjunctivitis is a reaction to various antigens and is characterized by itching and redness of the eye.

There are currently various products approved for use in allergic conjunctivitis. Some are labeled for ocular itching only. Others are labeled for allergic conjunctivitis, because the clinical studies demonstrated efficacy in both reducing ocular itching and ocular redness (conjunctivitis).

Lastacaft	Alcaftadine (#)	Ocular itching
Optivar	Azelastine Hydrochloride (#)	Ocular itching
Bepreve	Bepotastine (#)	Ocular itching
Elestat	Epinastine Hydrochloride (#)	Ocular itching
Alocril	Nedocromil sodium (*)	Ocular itching

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