

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022388Orig1s000

Trade Name: ACUVUE Theravision with Ketotifen

Generic or Proper Name: etafilcon A drug-eluting contact lens with ketotifen

Sponsor: Johnson & Johnson Vision Care, Inc.

Approval Date: March 3, 2022

Indication: For the prevention of ocular itch due allergic conjunctivitis and correction of refractive ametropia (myopia and hyperopia) in aphakic and/or phakic patients who do not have red eye(s) are suitable for contact lens wear and do not have more than 1.00 D of astigmatism.

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APPROVAL LETTER



NDA 022388

NDA APPROVAL

Johnson & Johnson Vision Care, Inc.
Attention: Ms. Catherine Dillon
Director, Regulatory Affairs
7500 Centurion Parkway
Jacksonville, FL 32256

Dear Ms. Dillon:

Please refer to your new drug application (NDA) dated April 30, 2021, received April 30, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for ACUVUE Theravision with Ketotifen (etafilcon A drug-eluting contact lens with ketotifen).

This NDA provides for the use of ACUVUE Theravision with Ketotifen (etafilcon A drug-eluting contact lens with ketotifen) for the prevention ocular itch due to allergic conjunctivitis and correction of refractive ametropia (myopia and hyperopia) in aphakic and/or phakic patients who do not have red eye(s), are suitable for contact lens wear and do not have more than 1.00 D of astigmatism.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Instruction Guide, and Fitting Instruction Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.² The SPL will be accessible via publicly available labeling repositories.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 022388.**” Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for ACUVUE Theravision with Ketotifen (etafilcon A drug-eluting contact lens with ketotifen) shall be 18 months from the date of manufacture when stored at 15-25°C. The expiration date for the packaged product, ACUVUE Theravision with Ketotifen (etafilcon A drug-eluting contact lens with ketotifen) shall be dependent on the shortest expiration date of any component.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for ages 0 to 11 years because necessary studies are impossible or highly impracticable. There are too few pediatric patients with allergic conjunctivitis and the concomitant need for corrective vision contact lenses under 11 years of age. The product has been assessed and labeled for pediatric patients 11 years and older.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

³ For the most recent version of a guidance, check the FDA guidance web page at

<https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.⁶

If you have any questions, please contact Ahmed Ayodeji, PharmD, at 301-796-1600.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Instruction Guide
 - Fitting Instruction Guide
- Carton and Container Labeling

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

⁶ <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WILEY A CHAMBERS
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