

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

215019Orig1s000

Trade Name: Dartisla ODT orally disintegrating tablets

Generic or Proper Name: Glycopyrrolate

Sponsor: Edenbridge Pharmaceuticals, LLC

Approval Date: December 16, 2021

Indication: Dartisla ODT orally disintegrating tablets is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

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APPROVAL LETTER



NDA 215019

NDA APPROVAL

Edenbridge Pharmaceuticals, LLC
Attention: Rekha Chappidi
Director, Regulatory Affairs
169 Lackawanna Avenue
Suite 110
Parsippany, NJ 07054

Dear Ms. Chappidi:

Please refer to your new drug application (NDA) dated and received February 26, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dartisla ODT (glycopyrrolate) orally disintegrating tablets.

This NDA provides for the use of Dartisla ODT (glycopyrrolate) orally disintegrating tablets in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter with minor editorial revisions listed below and reflected in the enclosed labeling:

- Revised formatting for Highlights and Table of Contents to fit all the information on the first page.

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) as well as annual reportable changes not included in the enclosed labeling. 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

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>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

We acknowledge your December 1, 2021 submission containing the final printed blister label and December 10, 2021 submission containing the final printed carton label.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Dartisla ODT (glycopyrrolate) orally disintegrating tablets shall be 24 months from the date of manufacture when stored at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [See USP Controlled Room Temperature].

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(ies) requirement for this application because this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in a substantial number of pediatric patients. Peptic ulcer disease is uncommon in the pediatric population in the United States and other existing therapies are effective in ulcer healing in children.

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>

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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Kelly Richards, Senior Regulatory Health Project Manager, at (240) 402-4276 or email at kelly.richards@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Juli Tomaino, MD, MS
Deputy Director
Division of Gastroenterology
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - o Prescribing Information
- Carton and Container Labeling

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/

JULI A TOMAINO
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