CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

214278Orig1s000

Trade Name:	
Generic or Proper Name:	esomeprazole delayed-release orally disintegrating tablets
Sponsor:	Dexcel Pharma Technologies Ltd.
Approval Date:	October 20, 2020
Indication:	For the use of esomeprazole delayed-release orally disintegrating tablets, 20mg for the treatment of frequent heartburn (occurs 2 or more days a week) in adults (18 years of age and older)

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APPROVAL LETTER

NDA 214278

NDA APPROVAL

Dexcel Pharma Technologies Ltd.
Attention: Jeanne M. Novak, PhD (Authorized Agent)
Chief Executive Officer and Principal Consultant
CBR International Corporation
2905 Wilderness Place, Ste. 202
Boulder, CO 80301

Dear Dr. Novak:

Please refer to your new drug application (NDA) dated and received December 20, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for esomeprazole delayed-release orally disintegrating tablets, 20 mg.

This new drug application provides for the use of esomeprazole delayed-release orally disintegrating tablets, 20 mg for the treatment of frequent heartburn (occurs 2 or more days a week) in adults (18 years of age and older).

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 agreed-upon labeling text and with the minor editorial revisions listed below.

1. In Drug Facts labeling (DFL), make the initial "i" lower case in the word "information" in the "Other information" heading.

2. Rotate the arrow in the "Inactive ingredients" heading left 90º to point the consumer to the next DFL heading (Questions) on the side panel accurately on the following labeling:
   - 2-count outer carton with berries image (physician sample)
   - 2-count outer carton without berries image (physician sample)
   - 14-count inner carton with berries image
   - 14-count inner carton without berries image
   - 14-count outer carton with berries image
   - 14-count outer carton without berries image

3. Rotate the last panel of the DFL by 180 degrees so that the text does not appear upside down when following the flow of information suggested by the arrow under the "Other information" heading on the following labeling:

- 28-count inner carton with berries image
- 28-count inner carton without berries image
- 42-count outer carton with berries image
- 42-count outer carton without berries image

4. Delete the three barlines enclosing the "Tips for managing heartburn" within the Drug Facts box. As proposed, the "Tips" list appears to be part of the Drug Facts box, but "Tips" is not required Drug Facts content. The list needs to appear outside of the Drug Facts box. Make this change to the following labeling:
   - 28-count inner carton with berries image
   - 28-count inner carton without berries image
   - 42-count outer carton with berries image
   - 42-count outer carton without berries image

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as the final printed labeling are available, but no more than 30 days after they are printed. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical (except for the above revisions) to the following labeling submitted on September 25, 2020 (items 1-10 below) and October 1, 2020 (items 11-12 below):

1. 2-count immediate container (blister)
2. 7-count immediate container (blister)
3. 2-count outer carton with berries image (physician sample)
4. 2-count outer carton without berries image (physician sample)
5. 14-count inner carton with berries image
6. 14-count inner carton without berries image
7. 14-count outer carton with berries image
8. 14-count outer carton without berries image
9. 28-count outer carton with berries image
10. 28-count outer carton without berries image
11. 42-count outer carton with berries image
12. 42-count outer carton without berries image

The final printed labeling should be submitted 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*.[1] For administrative purposes, designate this submission "**Final Printed**

[1] 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.

Labeling for approved NDA 214278." Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future (e.g., individual immediate containers containing greater than 14-count, total package sizes greater than 42-count), a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

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 this application because there is evidence strongly suggesting that the drug product would be ineffective and/or unsafe in

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

all pediatric age groups for over-the-counter use; the current position of the Agency is that heartburn in pediatric patients needs to be evaluated and treated by a physician.

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, call Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Acting Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

KAREN M MAHONEY
10/20/2020 03:34:03 PM