

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

204655Orig1s000

Trade Name: Nexium 24HR

Generic Name: Esomeprazole Delayed-Release Capsules, 20 mg.

Sponsor: ASTRAZENECA LP

Approval Date: March 28, 2014

Indications: For the treatment of frequent heartburn in adults 18 years of age and older.

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APPROVAL LETTER



NDA 204655

NDA APPROVAL

AstraZeneca, LP
Attention: Ian Hunt
Vice President, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Hunt:

Please refer to your New Drug Application (NDA), dated and received May 30, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium® 24HR (esomeprazole magnesium) delayed-release capsules, 20 mg.

We acknowledge receipt of your amendments dated June 25, July 10, September 27, October 18 and 31, November 18, and December 3 and 19, 2013; February 3, 20, and 25, and March 24 and 27, 2014.

This NDA provides for the use of Nexium® 24HR (esomeprazole magnesium) delayed-release capsules for the treatment of frequent heartburn 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.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following labeling submitted on March 27, 2014: 2-count and 14-count immediate containers (bottle), 2-count sample carton, 14-, 28- and 42-count carton labels and 14-, 28- and 42-count “Club” carton with backer card labels. The FPL must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 204655.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug. After six months of marketing, delete the “New” graphic on the labeling.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because 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 questions, contact Jeffrey Buchanan, Regulatory Project Manager,
at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
03/28/2014