

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

22-556Orig1s000

Trade Name: Karbinal ER extended-release oral suspension 4 mg/5mL.

Generic Name: carbinoxamine maleate

Sponsor: Tris Pharma, Inc.

Approval Date: March 28, 2013

Indications: Provides for the use of Karbinal ER, for relief of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled, and amelioration of the severity of allergic reactions to blood or plasma..

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APPROVAL LETTER



NDA 22556

NDA APPROVAL

Tris Pharma, Inc.
2033 Route 130, suite D
Monmouth Junction, NJ 08852

Attention: W. Scott Groner
Director Regulatory Affairs

Dear Mr. Groner:

Please refer to your New Drug Application (NDA) dated December 7, 2010, received December 8, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Karbinal ER (carbinoxamine maleate) extended-release oral suspension 4 mg/5mL.

We also acknowledge receipt of your amendments dated, December 29, 2010, and January 20, February 17, April 14, June 3, 10, 24, and 30, July 14, August 12, and 19, September 9, and 21, and November 17, 2011, and October 4, and 16, and December 6, 2012, and January 8, February 14, March 5, 11, 12, 13, 22, and March 27, 2013.

The October 4, 2012, submission constituted a complete response to our October 7, 2011, action letter.

This new drug application provides for the use of Karbinal ER, for relief of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled, and amelioration of the severity of allergic reactions to blood or plasma.

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.

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(1)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert). 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

We acknowledge your March 27, 2013, submission containing final printed carton and container labels.

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 ages birth to 23 months because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. The immediate release carbinoxamine maleate is contraindicated in patients less than 2 years of age due to deaths in this age group.

This product is appropriately labeled for use in ages 2 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Jessica Lee, Regulatory Project Manager, at (301) 796-3769.

Sincerely,

{See appended electronic signature page}

Lydia Gilbert McClain, MD
Deputy Director
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
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/

LYDIA I GILBERT MCCLAIN
03/28/2013