

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202513Orig1s000

Trade Name: ANTUROL

Generic Name: Oxybutynin gel 3%, for topical use

Sponsor: Antares Pharma, Inc.

Approval Date: 12/07/2011

Indications: for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

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APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202513/Original 1

NDA APPROVAL

Antares Pharma, Inc.
Attention: Kaushik J. Dave, R.Ph., Ph.D., M.B.A.
Senior Vice President Product Development
250 Phillips Blvd, Suite 290
Ewing, NJ 08618

Dear Dr. Dave:

Please refer to your New Drug Application (NDA) dated December 17, 2010, received February 8, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ANTUROL (oxybutynin), 3% gel.

We acknowledge receipt of your amendments dated February 14, March 10, April 6, 21, May 4, 5, 6, July 8, 22, 29, August 5, October 7, 17, November 4, 9, and December 1, 2011.

NDA 202513 provides for the use of ANTUROL (oxybutynin), 3% gel for treatment of overactive bladder with symptoms of urinary incontinence, urgency and frequency, proposing the following dosages which, for administrative purposes, we have designated as follows:

- NDA 202513/Original 1 – 84 mg

(b) (4)

The subject of this action letter is NDA 202513/Original 1.

(b) (4)

(b) (4)

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 indicated in the enclosed 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Package Insert and Patient Information). 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>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 Carton and Container Labels for approved NDA 202513.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 this product does not represent a meaningful therapeutic benefit over existing approved therapies for pediatric patients and is not expected to be used in a substantial number of pediatric patients.

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 Office of Prescription Drug Promotion, 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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director, Acting
Division of Reproductive and Urologic
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:

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/

AUDREY L GASSMAN
12/07/2011