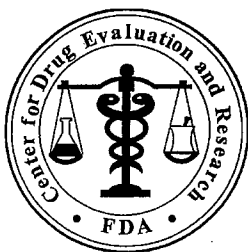


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-204

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: December 17, 2008

To: Scott Monroe, M.D., Director
Division of Reproductive & Urologic Products

Through: Jodi Duckhorn, MA, Team Leader
**Patient Labeling and Education Team
Division of Risk Management**

From: Nancy Carothers, RN
Patient Product Information Reviewer
**Patient Labeling and Education Team
Division of Risk Management**

Subject: Memo to File regarding DRISK Review of Patient Labeling
(Patient Package Insert)

Drug Name(s): GELNIQUE (10% oxybutynin chloride topical gel)

Application Type/Number: NDA 22-204

Applicant/sponsor: Watson Pharma, Inc.

OSE RCM #: 2008-1751

Please be advised at this time the Patient Labeling & Education Team is unable to complete a line-by-line review of the requested patient labeling for the above referenced consult. This is due to no fault of DRUP, and strictly based on the limited resources to handle the current workload. We would be happy to attempt to complete this review the next time this product is submitted to the Agency for review. DRUP would need to submit a new consult at that time. Our general recommendations in this memo are consistent with current research to improve risk communication to a broad audience, including those with lower literacy.

GENERAL RECOMMENDATIONS

1. In 2008, The American Society of Consultant Pharmacists Foundation in collaboration with The American Foundation for the Blind published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. They recommend using fonts such as Arial, Verdana, or APHont to make medical information more accessible for patients with low vision. We recommend that the Sponsor reformat the PPI using the font APHont, which was developed by the American Printing House for the Blind specifically for low vision readers.

2. Flesch Kinkaid grade level and Flesch Reading Ease scores were reviewed for DRAFT GELNIQUE Patient Package Insert (PPI):

- Flesch Reading Ease: 54.7
- Flesch-Kincaid Grade Level: 8.4

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60% (60% corresponds to an 8th grade reading level). The reading scores for the document as submitted by the sponsor are acceptable.

- We believe that with minimal changes, the scores could be lowered to a level that would make the PPI easier to comprehend by most users of GELNIQUE:

1. replace the word (b) (4) with "itching"
2. replace the word (b) (4) with "redness"
3. replace the word (b) (4) with "packet"
4. replace the sentence, (b) (4) with "Once you have applied the gel, do not let the area get wet for one hour. Avoid activities such as bathing, swimming, showering, and exercising."

- To clarify the Steps that describe the application of the product, we suggest:

Step 1, Replace the first sentence with: "The approved application sites for GELNIQUE are the shaded areas in Figure A. These are the abdomen (stomach area), upper arms and shoulder, and thigh.

Add "Figure A" to the illustration.

Step 4, Replace the word (b) (4) with packet in the first and fourth sentences:

“Tear the packet of GELNIQUE open at the indentation just before use. See Figure B.
“The contents of the packet can also be squeezed directly onto the application site.”

Add “Figure B” to the illustration.

Step 4 Change the last sentence to: “It will be about the size of a nickel. See Figure C.
Add “Figure C to the illustration showing the gel on the finger tips.

Step 5, add “See Figure D.” at the end of the description on applying the gel.
Add “Figure D” to the illustration.

- A medicine that is similar to GELNIQUE is TOVIAZ™ (fesoterodine fumarate). It is prescribed for overactive bladder. Although it is in tablet form, we recommend using the Toviaz PPI as a guide as applicable.
- We also recommend including the following immediately after the information about the possible side effects of GELNIQUE:
“Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of GELNIQUE. For more information, ask your doctor or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.”

Please contact us with any questions.

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

/s/

Nancy B Carothers
12/17/2008 09:34:02 AM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
12/17/2008 09:53:12 AM
DRUG SAFETY OFFICE REVIEWER