CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 22-206

OTHER REVIEWS

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Maternal Health Team Review

Date: September 18, 2008 **Date Consulted:** September 4, 2008

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To: Division of Reproductive and Urologic Products (DRUP)

Drug: Rapaflo (silodosin), NDA 22-206

Subject: Pregnancy and Nursing Mothers labeling

Materials Reviewed: Pregnancy and Nursing Mothers subsections of Rapaflo labeling.

Consult Question: Please review the Pregnancy and Nursing Mothers subsections of labeling.

INTRODUCTION

On December 12, 2007 Watson Pharmaceuticals submitted a new drug application (NDA) 22-206 to the Division of Reproductive and Urologic Products (DRUP) for Rapaflo. The sponsors proposed indication for Rapaflo is for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

On September 4, 2008, the Safety Endpoints and Labeling Development (SEALD) Team consulted the Maternal Health Team (MHT) to review the pregnancy and nursing mothers section of the Rapaflo package insert, and provide comment. This review provides revisions to the sponsors proposed Pregnancy and Nursing Mothers subsections of Rapaflo labeling.

BACKGROUND

The MHT and the SEALD Team have been working together to develop a more consistent and clinically useful approach to the Pregnancy and Nursing Mothers subsections of labeling. This approach complies with current regulations but incorporates "the spirit" of the Proposed Pregnancy and Lactation Labeling Rule (published on May 28, 2008).

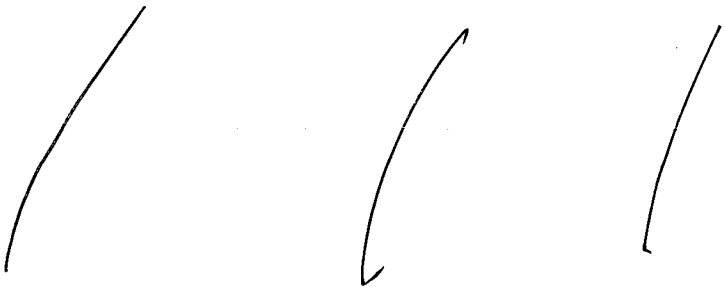
As part of the labeling review, the MHT reviewer conducts a literature search to determine if relevant published pregnancy and lactation data are available that would add clinically useful information to the pregnancy and nursing mothers label subsections. In addition, the MHT presents available animal data, in the pregnancy subsection, in an organized, logical format that makes it as clinically relevant as possible for prescribers. This includes expressing animal data in terms of species exposed, timing and route of drug administration, dose expressed in terms of human dose equivalents (with the basis for calculation), and outcomes for dams and offspring. For nursing mothers, when animal data are available, only the presence or absence of drug in milk is considered relevant and presented in the label, not the amount.

This review provides revisions to the sponsors proposed Pregnancy and Nursing Mothers subsections of Rapaflo labeling.

SUMBMITTED MATERIAL

Sponsors Proposed Pregnancy and Nursing Mothers Labeling

8.1 Pregnancy



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✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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CONCLUSIONS

While the Proposed Pregnancy and Lactation Labeling Rule, published May 2008, is in the clearance process, the MHT is structuring the Pregnancy and Nursing Mothers label information in a way that is in the spirit of the Proposed Rule while still complying with current regulations. The goal of this restructuring is to make the pregnancy and lactation sections of labeling a more effective communication tool for clinicians.

The MHT's recommended labeling for Rapaflo is provided on pages 3-4 of this review. Appendix A of this review also provides a track changes version of labeling.

Appendix A –
Track Changes Version of Labeling

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✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)