CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-308

MICROBIOLOGY REVIEW

Microbiology Review

Division of Special Pathogen and Immunologic Drug Products

(HFD-590)

NDA# 21-308

Reviewer : Linda Gosey
Correspondence Date : 8-31-2000
CDER Receipt Date : 9-01-2000
Review Assigned Date: 6-25-2001
Review Complete Date: 6-27-2001

Sponsor: [redacted]

Submission Reviewed: Original

Drug Category: Vaginal antifungal

Indication: Treatment of vulvovaginal candidiasis

Dosage Form: Soft gel vaginal insert/external cream

Product Names:

a. Proprietary: Monistat Dual-Pak

b. Nonproprietary: Miconazole nitrate (1200 mg vaginal ovule) with 2% miconazole nitrate cream (external use)

c. Chemical: 1-[2,4-dichloro-B-[(2,4,-dichlorobenzyl)oxyl] phenethyl] imidazole nitrate

Supporting Documents: [redacted] NDA 20-968

NDA 21-308
Monistat 1 (1200 mg ovule) and external cream
Advanced Care Products

Background:

Miconazole nitrate was first approved in 1974 as a vaginal cream (2%, 100 mg) to be dosed daily for 14 days for the treatment of vaginal candidiasis. In May of 1999 the 1200 mg miconazole nitrate ovule in combination with the use of the 2% external vulvar cream was approved for prescription use. In this NDA the sponsor is seeking approval for over-the-counter (OTC) use of the 1200 mg miconazole nitrate ovule in combination with the use of the 2% external vulvar cream. The proposed population for OTC use, females with occasional and recurrent episodes ($\leq$4 infections/year) of vulvovaginal candidiasis, is the same as that described for prescription use.

Summary:

Preclinical Microbiology:

In this NDA package there is no new preclinical microbiology information. The activity profile of miconazole nitrate against Candida strains has been described in detail in the microbiology review of NDA 20-968 dated 6-30-98. Because miconazole is already approved for the treatment of vaginal candidiasis it is not necessary to conduct another formal review of the preclinical microbiology data.

Clinical Microbiology:

In NDA 20-968, the sponsor demonstrated equivalent efficacy between the 1200 mg miconazole nitrate ovule, single treatment with the 2% miconazole nitrate external cream and the 7 day treatment course with 200 mg miconazole nitrate cream. As a consequence, there are no new clinical microbiology data to review in this NDA package.

Conclusions:

In conclusion, with respect to microbiology there are no safety or efficacy concerns and the proposed indication for OTC use of the 1200 mg miconazole nitrate ovule, single treatment, with the 2% miconazole nitrate external cream should be approved.

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Recommendations:

There are no microbiology recommendations to be conveyed to the sponsor at this time.

Linda L. Gosey
Microbiologist (HFD 590)

Concurrences:
HFD-590/Dep Dir _____Signature_____Date
HFD-590/Micro TL_____ Signature_____Date
CC:
HFD-590/ Orig.NDA#21-308
HFD-590/ Division File
HFD-590/MO:Hu
HFD-590/CSO:Chi
HFD-590/Chem:Matecka
HFD-590/Pharm
HFD-590/Review Micro:Gosey