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RESEARCH**

APPLICATION NUMBER:
74-926

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 74-926

3. NAME AND ADDRESS OF APPLICANT

Alpharma, U.S. Pharmaceuticals Division
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

4. LEGAL BASIS FOR SUBMISSION

The firm has indicated that Monistat 3 combination pack is entitled to a period of marketing exclusivity which expires on April 16, 1999.
NMC does not intend to introduce product into the market place prior to the expiration of this exclusive marketing period.

7. NONPROPRIETARY NAME

Miconazole Nitrate Vaginal Suppositories/Miconazole Nitrate Cream

9. AMENDMENTS AND OTHER DATES:

Original 7/15/96
Amendment 8/14/96
Amendment 2/13/98
Amendment 4/3/98
Amendment 4/20/98
Amendment 1/29/99
Amendment 3/26/99

10. PHARMACOLOGICAL CATEGORY

Treatment of vaginal yeast infections and the relief of external vulvar itching and irritation associated with a yeast infection

11. Rx or OTC

OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

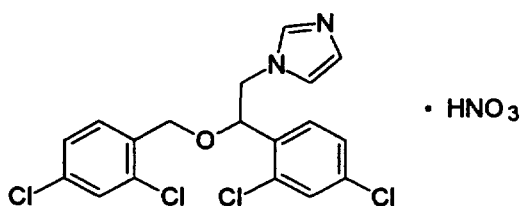
Vaginal Suppositories/Vaginal Cream

14. POTENCY

200 mg/2%

15. CHEMICAL NAME AND STRUCTURE

Miconazole Nitrate. 1*H*-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate. C₁₈H₁₄Cl₄N₂O•HNO₃. 479.15. 22832-87-7. Antifungal. USP 23, page 1026.



17. COMMENTS: Previously tentatively approved. No significant changes. Added bulk uniformity testing.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

4/7/99

Supervisor: Paul Schwartz, Ph.D.

4/7/99

Cc:

Endorsements:

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem. Rev 3

4/7/99