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RESEARCH**

APPLICATION NUMBER:

75-581

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3 (three)

2. ANDA # 75-581

3. NAME AND ADDRESS OF APPLICANT

Teva Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443

4. LEGAL BASIS FOR SUBMISSION

This application refers to the listed drug Nizoral® (ketoconazole) 2% Cream. Patent certification: The undersigned hereby (Debrah A. Jaskot, Sr. Director, regulatory affair) certifies that to the best of our knowledge and in Teva pharmaceuticals USA's opinion there is one patent which claims the listed drug Nizoral® (ketoconazole) 2% Cream. U.S. Patent No. 4335125 Expiration June 15, 1999. In accord with Section 505 (j)(2)(A)(vii)(III) of the Food, Drug and cosmetic Act, as amended, TEVA pharmaceuticals USA certifies U.S. Patent #4335125 will expire on June 15, 1999.

Exclusivity statement:

The undersigned hereby (Deborah A. Jaskot, Sr. Director, Regulatory Affairs) certifies that to the best of our knowledge and in Teva pharmaceuticals USA's opinion, there exist no listed exclusivities for the referenced drug product, Nizoral® (ketoconazole) 2% Cream.

Certification made pursuant to the generic drug enforcement act of 1992 is included (page 17).

Addendum to form FDA 3454:

Certification: financial interest and arrangements of clinical investigators is included in pages 18A and 18B.

5. SUPPLEMENT (s)

None

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Ketoconazole Cream, 2%

8. SUPPLEMENT (s) PROVIDE (s) FOR:

None

9. AMENDMENTS AND OTHER DATES:

Date of submission: February 12, 1999

Major amendment: September 20, 1999

Fax amendment: March 16, 2000

Telephone amendment: April 6, 2000

10. PHARMACOLOGICAL CATEGORY

antifungal (for the topical treatment of tinea corporis)

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF (s)

Nizoral® cream 2%

NDA# 19084 (Dec 31, 1985 approval date)

Patent expiration: June 15, 1999

NDA holder: Janssen Pharmaceutica

13. DOSAGE FORM

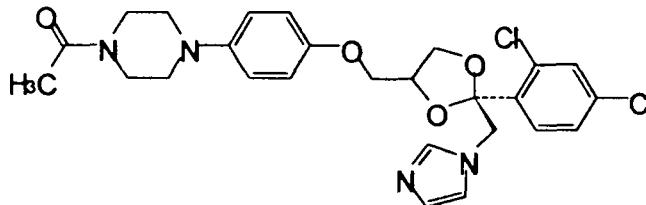
Cream

14. POTENCY

2%

15. CHEMICAL NAME AND STRUCTURE

Ketoconazole. $C_{26}H_{28}Cl_2N_4O_4$. 531.44. Piperazine, 1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazole-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-, cis-. 65277-42-1. Antifungal.



16. RECORDS AND REPORTS

None

17. COMMENTS

This application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

This application is approvable.

19. REVIEWER:

Liang-Lii Huang, Ph.D.

DATE COMPLETED:

March 29, 2000

Endorsed by Paul Schwartz, Ph.D. /March 29, 2000

Page(s)

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Chem Rev 3

3/29/00

1. CHEMISTRY REVIEW NO. 2 (two)
2. ANDA # 75-581
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443
4. LEGAL BASIS FOR SUBMISSION
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Exclusivity statement:
The undersigned hereby (Deborah A. Jaskot, Sr. Director, Regulatory Affairs) certifies that to the best of our knowledge and in Teva pharmaceuticals USA's opinion, there exist no listed exclusivities for the referenced drug product, Nizoral® (ketoconazole) 2% Cream.
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5. SUPPLEMENT(s)
None
6. PROPRIETARY NAME
None
7. NONPROPRIETARY NAME
Ketoconazole Cream, 2%
8. SUPPLEMENT(s) PROVIDE(s) FOR:
None
9. AMENDMENTS AND OTHER DATES:
Date of submission: February 12, 1999
Major amendment: September 20, 1999
10. PHARMACOLOGICAL CATEGORY
antifungal (for the topical treatment of tinea corporis)
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NDA# 19084 (Dec 31, 1985 approval date)
Patent expiration: June 15, 1999
NDA holder: Janssen Pharmaceutica

Page(s)

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Chem Rev 2

2/16/00

1. CHEMISTRY REVIEW NO. 1 (one)
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3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443
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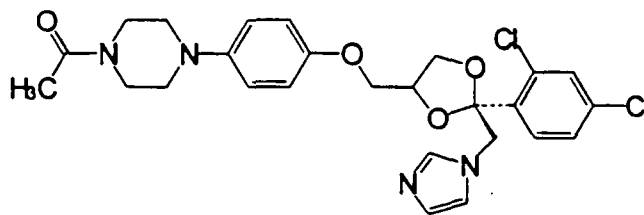
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16. RECORDS AND REPORTS

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17. COMMENTS

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18. CONCLUSIONS AND RECOMMENDATIONS

This application is not approvable.

19. REVIEWER:

Liang-Lii Huang, Ph.D.

DATE COMPLETED:

June 30, 1999

Endorsed by Paul Schwartz, Ph.D. /June 30, 1999

Cc:

Enc

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Chem Rev

6/30/99