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ATTORNEYS FOR PLAINTIFF MCNEIL-PPC, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MCNEIL-PPC, INC., **Plaintiff,** **v.** **PERRIGO COMPANY, L. PERRIGO COMPANY, and PERRIGO RESEARCH & DEVELOPMENT COMPANY,** **Defendants.**	Civil Action No. _____ Filed Electronically

COMPLAINT

Plaintiff McNeil-PPC, Inc. ("McNeil-PPC"), for its complaint for patent infringement against Defendants Perrigo Company, L. Perrigo Company, and Perrigo Research & Development Company, alleges as follows:

PARTIES

1. Plaintiff McNeil-PPC is a New Jersey Corporation with its principal place of business at 199 Grandview Road, Skillman, New Jersey 08558-9418.

2. Upon information and belief, defendant Perrigo Company is a corporation organized under the laws of the State of Michigan, having a principal place of business at 515

Eastern Ave., Allegan, Michigan 49010. Upon information and belief, Perrigo Company is registered to do business in New Jersey and conducts business in New Jersey.

3. Upon information and belief, defendant L. Perrigo Company is a corporation organized under the laws of the State of Michigan, having a place of business at 1267 S River Road, Cranbury, New Jersey 08512.

4. Upon information and belief, defendant Perrigo Research & Development Company is a corporation organized under the laws of the State of Michigan, having a place of business at 515 Eastern Ave., Allegan, Michigan 49010.

5. Upon information and belief, defendants L. Perrigo Company and Perrigo Research & Development Company are wholly owned subsidiary companies of defendant Perrigo Company.

6. Upon information and belief, the acts of Perrigo Research & Development Company complained of herein were aided by and done with the authorization, cooperation, participation, or assistance of Perrigo Company and L. Perrigo Company.

7. Defendants Perrigo Company, L. Perrigo Company, and Perrigo Research & Development Company are hereinafter referred to collectively as "Perrigo."

8. Upon information and belief, Perrigo is in the business, inter alia, of manufacturing generic drug products for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271.

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Upon information and belief, Perrigo Company, L. Perrigo Company, and Perrigo Research & Development Company, directly or through related companies, have continuous and systematic contacts within this judicial district, sell a substantial amount of products in New Jersey, and regularly conduct business in New Jersey.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT FOR PATENT INFRINGEMENT

13. McNeil-PPC is the owner of United States Patent No. 6,153,635 (the "635 Patent") entitled "Methods and Kits for Treating Vulvovaginal Candidiasis with Miconazole Nitrate." The 635 Patent duly and legally issued on November 28, 2000. A true and correct copy of the 635 Patent is attached as Exhibit A to this Complaint.

14. Pursuant to 21 U.S.C. § 355(b)(1), the 635 Patent is identified in the Food and Drug Administration publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in association with Miconazole Nitrate Vaginal Cream (2%) and Suppository (1.2g).

15. McNeil-PPC received a letter from Perrigo Research & Development Company, dated March 6, 2008 and received on March 7, 2008, that gave notice that Perrigo had filed an Abbreviated New Drug Application ("ANDA") No. 79-114 with the Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) to obtain FDA approval to engage in the commercial manufacture, use or sale of Miconazole Nitrate Vaginal Cream (2%) and Suppository (1.2g) prior to the expiration of the 635 Patent.

16. Perrigo's ANDA No. 79-114 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") in which Perrigo alleges that its ANDA product will not infringe claims 1-7 and 11 of the 635 Patent and that all claims of the 635 Patent are invalid.

17. Perrigo's commercial manufacture, use, offer for sale, or sale of its proposed generic Miconazole Nitrate Vaginal Cream (2%) and Suppository (1.2g) would infringe the 635 Patent.

18. Because Perrigo submitted an ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of Miconazole Nitrate Vaginal Cream (2%) and Suppository (1.2g) prior to the expiration of the 635 Patent, Perrigo has infringed the 635 Patent pursuant to 35 U.S.C. § 271(e)(2)(A).

19. McNeil-PPC will be irreparably harmed if Perrigo is not enjoined from infringing the 635 Patent, and McNeil-PPC is entitled to equitable relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff McNeil-PPC respectfully demands the following relief:

(a) entry of a final judgment that Defendants have infringed the 635 Patent by submitting ANDA No. 79-114;

(b) entry of a final judgment that this is an exceptional case pursuant to 35 U.S.C. § 285, and that Plaintiff is entitled to reasonable attorneys' fees;

(c) to the extent that Defendants have committed any acts with respect to what is claimed in the 635 Patent, other than those acts expressly exempted under 35 U.S.C. § 271(e)(1), an award of damages sufficient to compensate Plaintiff for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(d) a permanent injunction, issued pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of products the use of which would infringe the 635 Patent;

(e) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 79-114 be a date which is not earlier than the expiration of the 635 Patent, or any later expiration of exclusivity to which the 635 Patent is or becomes entitled;

(f) an award of Plaintiff's costs and expenses in this action; and

(g) such other relief as the Court may deem just and proper.

s/Thomas E. Hastings
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ATTORNEYS FOR PLAINTIFF MCNEIL-PPC, INC.

Dated: April 18, 2008

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

I hereby certify that to my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/Thomas E. Hastings
Thomas E. Hastings

Dated: April 18, 2008

EXHIBIT A

US006153635A

United States Patent [19]

Upmalis

[11] **Patent Number: 6,153,635**

[45] **Date of Patent: Nov. 28, 2000**

[54] **METHODS AND KITS FOR TREATING VULVOVAGINAL CANDIDIASIS WITH MICONAZOLE NITRATE**

[76] Inventor: **David H. Upmalis**, 51 Declaration Dr., Newtown, Pa. 18940

[21] Appl. No.: **09/197,019**

[22] Filed: **Nov. 20, 1998**

[51] **Int. Cl.**[7] **A61K 31/415**

[52] **U.S. Cl.** **514/399**; 514/931

[58] **Field of Search** 514/399, 931

[56] **References Cited**

PUBLICATIONS

Olin, B.R. et al., Facts and Comparisons, St. Louis, MO: JB Lippincott Co. (Oct. 1985) pp. 355a–355b.

Olin, B.R. et al., Facts and Comparisons, St. Louis, MO: J.B. Lippincott Co. (Nov. 1989), pp. 528–530.

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[57] **ABSTRACT**

A method for treating vulvovaginal candidiasis including the steps of: (a) administering a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier intra-vaginally; and (b) applying miconazole nitrate in a pharmaceutically acceptable carrier to the vulva. Also a kit for the treatment of vulvovaginal candidiasis including: (a) a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier and in a form adapted to be administered intra-vaginally; and (b) an amount of miconazole nitrate in a pharmaceutically acceptable carrier adapted to be applied topically to the vulva.

13 Claims, No Drawings

METHODS AND KITS FOR TREATING VULVOVAGINAL CANDIDIASIS WITH MICONAZOLE NITRATE

FIELD OF THE INVENTION

The present invention relates to methods for the treatment of vulvovaginal candidiasis with miconazole nitrate and more particularly to methods for the treatment of vulvovaginal candidiasis employing a single dose of miconazole nitrate applied intra-vaginally and additional doses of miconazole nitrate applied topically to the vulva.

BACKGROUND OF THE INVENTION

Vulvovaginal candidiasis is a relatively common form of yeast infection. Treatment of vulvovaginal candidiasis with the anti-fungal composition miconazole nitrate is well known. The most common regimen of treatment of vulvovaginal candidiasis with miconazole nitrate comprises the intra-vaginal application of a cream or other pharmaceutically acceptable carrier containing miconazole nitrate once a day for 1, 3 or 7 days depending upon the concentration of miconazole nitrate in the cream. Thus, commercial kits for the treatment of vulvovaginal candidiasis with miconazole nitrate comprise a supply of vaginal suppositories or cream containing miconazole nitrate and a suitable applicator for administering the miconazole nitrate intra-vaginally.

While these methods of treating vulvovaginal candidiasis are highly effective, there is a certain amount of discomfort and inconvenience for the patient in having to repeatedly administer the miconazole nitrate intra-vaginally. Both of these disadvantages can affect patient compliance and, therefore, the effectiveness of the treatment. In addition, relief of symptoms can take 4–5 days or more.

Accordingly, there is a need for improved methods for treating vulvovaginal candidiasis with miconazole nitrate that are more convenient and comfortable than known methods and that provide faster relief of vulvovaginal candidiasis.

SUMMARY OF THE INVENTION

The present invention is directed to a method for treating vulvovaginal candidiasis consisting essentially of the steps of: (a) administering a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier intra-vaginally; and (b) applying miconazole nitrate in a pharmaceutically acceptable carrier to the vulva.

The present invention is also directed to a kit for the treatment of vulvovaginal candidiasis comprising: (a) a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier and in a form adapted to be administered intra-vaginally; and (b) an amount of miconazole nitrate in a pharmaceutically acceptable carrier adapted to be applied topically to the vulva.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

It has been discovered that the intra-vaginal administration of a single dose of miconazole nitrate in combination with the topical administration of a miconazole nitrate cream to the vulva is at least as effective as previously known treatment regimens comprising 3 to 7 daily intra-vaginal doses of miconazole nitrate and results in faster relief of vulvovaginal candidiasis symptoms. In particular, studies comparing the effectiveness of standard 7 day miconazole nitrate intra-vaginal treatment regimens to treatment regimens comprising a single intra-vaginal dose of miconazole nitrate in combination with a miconazole nitrate cream applied topically to the vulva found that the single dose miconazole nitrate intra-vaginal treatment in combination with a topical miconazole nitrate cream resulted in faster therapeutic cure rates and equivalent microbiological and clinical cure rates. Similar comparisons of 3 day to 7 day therapies have not shown such an effect.

Methods for treating vulvovaginal candidiasis with miconazole nitrate in accordance with the present invention comprise the steps of: (a) administering a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier intra-vaginally; and (b) applying miconazole nitrate in a pharmaceutically acceptable carrier to the vulva as needed.

The dose of miconazole nitrate in a pharmaceutically acceptable carrier administered intra-vaginally may be in the form of a gelatin capsule, a cream, or any other intra-vaginal delivery system. The intra-vaginal dose of miconazole nitrate preferably comprises from about 400–2000 mg of miconazole nitrate, more preferably from about 600–1200 mg of miconazole nitrate. Delivery systems and phamaceutically acceptable carriers for intra-vaginally delivered miconazole nitrate are known to those of ordinary skill in the art.

The dose of miconazole nitrate applied to topically to the vulva may be a cream or other pharmaceutically acceptable carrier containing from about 1% to 4% mg miconazole nitrate in a form adapted to be applied topically. A preferred topical cream comprising 2% miconazole nitrate is marketed by Advanced Care Products, Personal Products Co. as MONISTAT® EXTERNAL VULVAR CREAM. It is believed that in addition to the synergistic effect of the combining the single intra-vaginal miconazole nitrate dose with the topical doses applied to the vulva, the topical doses provide for immediate temporary relief of vulvovaginal candidiasis symptoms. Accordingly, the dose of miconazole nitrate applied to the vulva is preferably applied 1–2 times daily as needed for up to about 7 days for the immediate temporary relief of vulvovaginal candidiasis symptoms.

The invention will be clarified further by a consideration of the following Examples, which are intended to be purely exemplary.

EXAMPLES

As used herein, "clinical cure" means that no symptoms of vulvovaginal candidiasis were detected upon physical examination. "Microbiological cure" means that a culture for candidiasis was negative. "Therapeutic cure" means that no additional treatment was indicated for vulvovaginal candidiasis

Example 1

A study was performed comparing results of treatment of vulvovaginal candidiasis with: (1) a single dose of 1200 mg of miconazole nitrate in a gelatin capsule in an ointment base administered intra-vaginally in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief); versus (2) MONISTAT®[7] Vaginal Cream.

The study population was as follows. 278 patients with vulvovaginal candidiasis were entered. 266 (96%) of the patients were valid for safety. 213 (77%) of the patients were valid for efficacy at return visit 1. 196 (71%) of the patients were valid for overall efficacy. About 60% of the patients

were white, with most of the remaining patients either hispanic or black. Mean age of the patients was 33–34 years. Just over one third of the patients reported oral contraceptive use. Disease severity was mild or moderate in over 90% of the patients. 4–7% of the patients reported severe disease. The two treatment groups appeared comparable at baseline.

Results of treatment in Example I are set forth in Tables 1 and 2.

TABLE 1

	GROUP 1: Miconazole Nitrate (1200 mg) Vaginal Ovule & MONISTAT® External Vulvar Cream (N = 99)		GROUP 2: MONISTAT® 7 Vaginal Cream (N = 97)	
Overall Cure Rate	n	%	n	%
Clinical	81	81.8	79	81.4
Microbiological	75	75.8	71	73.2
Therapeutic	71	71.7	68	70.1

TABLE 2

	GROUP 1: Miconazole Nitrate (1200 mg) Vaginal Ovule & MONISTAT® External Vulvar Cream		GROUP 2: MONISTAT® 7 Vaginal Cream	
Relief at 3 days	29/94	(30.9%)	15/92	(16.3%)
Relief at 7 days	66/94	(70.2%)	64/92	(69.6%)

Overall clinical, microbiological and therapeutic cure rates were almost identical in the two treatment groups. There was no statistically significant difference in the overall therapeutic cure rates (p=0.96). The 95% confidence intervals for the difference in overall cure rates, clinical cure rates (−10.5%, 11.2%), microbiological cure rates (−9.7%, 14.8%) and therapeutic cure rates (−11.1%, 14.3%) indicate that the two formulations are therapeutically equivalent. However, relief of itching and burning/irritation was significantly higher in Group 1 at Day 3 (p=0.025). Median time to symptom relief was four days in Group 1 and five days in Group 2.

Example 2

A study identical in design to that reported in Example 1 was performed on a second population. In Example 2, the study population was as follows. 280 patients with vulvovaginal candidiasis were entered. 271 (97%) of the patients were valid for safety. 205 (73%) of the patients were valid for efficacy at return visit 1. 194 (69%) of the patients were valid for overall efficacy. Somewhat fewer Group 2 patients were evaluable at both return visit 1 and overall because of more screening failures in this group. About 70% of patients were white, with most of the remaining patients either black or hispanic. Mean age of the patients was 36.3 years. About 20–25% of the patients reported oral contraceptive use. Disease severity was mild or moderate in over 95% of the patients. 2% of the patients reported severe disease. The two treatment groups appeared comparable at baseline.

Results of treatment in Example 2 are set forth in Tables 3 and 4.

TABLE 3

	GROUP 1: Miconazole Nitrate (1200 mg) Vaginal Ovule & MONISTAT® External Vulvar Cream (N = 104)		GROUP 2: MONISTAT® 7 Vaginal Cream (N = 90)	
Overall Cure Rate	n	%	n	%
Clinical	72	69.2	63	70.0
Microbiological	72	69.2	62	68.9
Therapeutic	64	61.5	55	61.1

TABLE 4

	GROUP 1: Miconazole Nitrate (1200 mg) Vaginal Ovule & MONISTAT® External Vulvar Cream		GROUP 2: MONISTAT® 7 Vaginal Cream	
Relief at 3 days	41/100	(41.0%)	19/85	(22.4%)
Relief at 7 days	66/100	(66.0%)	59/85	(69.4%)

Overall clinical, microbiological and therapeutic cure rates were almost identical in the two treatment groups. There was no statistically significant difference in the overall therapeutic cure rates (p=0.775). The 95% confidence intervals for the difference in overall cure rates, clinical cure rates (−13.7, 12.2), microbiological cure rates (−12.7, 13.4) and therapeutic cure rates (−13.3, 14.2) indicate that the two formulations are therapeutically equivalent. However, relief of itching and burning/irritation was significantly higher in Group 1 at day 3 (p=0.008). Median time to symptom relief was three days in Group 1 and four days in Group 2.

Example 3

A dose-ranging study was performed comparing: (1) various doses of miconazole nitrate in one-dose cream formulations in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief); against (2) MONISTAT® 7 Vaginal Cream.

Patients were randomized equally to one of the following five regimens:

Group 1: a single intra-vaginal dose of 2.5 grams of 16% miconazole nitrate vaginal cream containing 400 mg of miconazole nitrate in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief);

Group 2: a single intra-vaginal dose of 5 grams of 8% miconazole nitrate vaginal cream containing 400 mg of miconazole nitrate in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief);

Group 3: a single intra-vaginal dose of 5 grams of 12% miconazole nitrate vaginal cream containing 600 mg of miconazole nitrate in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief);

Group 4: a single intra-vaginal dose of 5 grams of 16% miconazole nitrate vaginal cream containing 800 mg of

miconazole nitrate in combination with MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief); and

Group 5: 7 daily doses of MONISTAT® 7 (2% miconazole nitrate) Vaginal Cream each containing 100 mg per dose of miconazole nitrate.

The study population was as follows. 230 patients with vulvovaginal candidiasis were entered. 228 (99%) of the patients were valid for safety. 186 (81%) of the patients were valid for efficacy. Mean ages of the patients by treatment groups were 34.5 years to 38.3 years. 59.1% to 72.9% of the patients were white, with most remaining patients classified as black or hispanic. Oral contraceptive use by treatment group ranged from 15.9% to 34.1%. Disease severity was mild or moderate in over 90% of the patients with severe disease reported in from 2.3% to 9.1% of the patients by treatment group. Despite some differences, the five treatment groups were reasonably comparable at baseline.

Results of treatment in Example 3 are set forth in Tables 5 and 6.

TABLE 5

	Clinical Cure		Microbiological Cure		Therapeutic Cure	
Study Group	n	%	n	%	n	%
Group 1	32/36	88/9	27/36	75.0	25/36	69.4
Group 2	36/37	97.3	27/37	73.0	27/37	73.0
Group 3	39/42	92/9	36/42	85.7	34/42	81.0
Group 4	35/38	92.1	35/38	92.1	32/38	84.2
Group 5	29/33	87.9	27/33	81.8	26/33	78.8

TABLE 6

	Symptomatic Relief at Day 3		Symptomatic Relief at Day 7	
Study Group	n	%	n	%
Group 1	7/34	21	22/34	65
Group 2	16/31	52	25/31	81
Group 3	13/39	33	31/39	79
Group 4	10/38	26	33/38	87
Group 5	4/29	14	20/29	69

Clinical, microbiological and therapeutic cure rates were acceptable for all five treatment regimens. Microbiological and therapeutic cure rates were highest in Groups 3 and 4. Proportions of patients obtaining symptomatic relief at 3 and 7 days varied widely, with the highest rates at both time intervals in Groups 2–4. Median time to relief of symptoms was also quite variable: 3 days in Group 2; 4 days in Groups 1 and 3; and 5 days in Groups 4 and 5. While statistical analysis was not performed on the Day 3 cure rates due to the smallness of the sample size, it appears that the cure rates on Day 3 are higher for Groups 1–4 (single intra-vaginal dose plus topical cream regimens) than Group 5 (7-day/dose intra-vaginal regimen).

Example 4

A study was performed comparing: (1) a regimen of MONISTAT® 3 Suppositories (200 mg miconazole nitrate) plus MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief); against (2) a regimen of MONISTAT® 7 Vaginal Cream (5-grams, 100 mg miconazole nitrate) plus MONISTAT® EXTERNAL VULVAR CREAM (with instructions to apply as necessary, up to twice daily, for symptomatic relief).

The study population was as follows. 263 patients were enrolled. 257 (98%) of the patients were valid for safety. 195 (74%) of the patients were valid for efficacy at return visit 1. 183 (70%) of the patients were valid for overall efficacy. Just over 60% of the patients were caucasian, and approximately 29% of the patients were black. Women on MONISTAT®3 were about two years older than women on MONISTAT®7 (36.3 vs. 34.7 years). Oral contraceptive use was less frequent on MONISTAT®3 (23% vs. 34%). More patients on MONISTAT®7 admitted to intercourse and did not always use a condom between admission and return visit 1, and also between return visits 1 and 2. Disease severity was mild or moderate in over 90% of the patients at baseline. The two groups appeared reasonably comparable overall.

Results of treatment in Example 4 are set forth in Table 7.

TABLE 7

Days to Relief in Patients Valid for Overall Efficacy

	Group 1: MONISTAT ® 3 Vaginal Suppositories & MONISTAT ® External Vulvar Cream	Group 2: MONISTAT ® 7 Vaginal Cream & MONISTAT ® External Vulvar Cream
Day 3	32/91 (35%)	20/90 (22%)
Day 7	63/91 (69%)	58/90 (64%)

Overall clinical, microbiological and therapeutic cure rates were comparable in the two treatment groups. Cure rates were also comparable in patients valid for efficacy at return visit 1. The difference between Groups 1 and 2 in symptomatic relief at day 3 was not statistically significant.

It will be understood by person by persons skilled in the art that various changes in the details, components, steps, and arrangements of the components and steps which have been described and illustrated in order to explain the nature of this invention may be made by those skilled in the art without departing from the principle and scope of the invention as expressed in the following claims.

What is claimed is:

1. A method for treating vulvovaginal candidiasis consisting essentially of the steps of:

(a) administering a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier intra-vaginally; and

(b) applying topically miconazole nitrate in a pharmaceutically acceptable carrier to the vulva.

2. The method of claim **1**, wherein the single dose of miconazole nitrate administered intra-vaginally comprises about 400 to about 2000 mg of miconazole nitrate.

3. The method of claim **1**, wherein the single dose of miconazole nitrate administered intra-vaginally comprises about 600 to about 1200 mg of miconazole nitrate.

4. The method of claim **1**, wherein the single dose of miconazole nitrate administered intra-vaginally comprises 2.5 g of 16% miconazole nitrate cream, 5 g of 8% miconazole nitrate cream, 5 g 12% miconazole nitrate cream or 5 g 16% miconazole nitrate cream.

5. The method of claim **1**, wherein step (b) is performed 1–2 times per day.

6. The method of claim **1**, wherein step (b) is performed 1–2 times per day for about 7 days.

7. The method of claim **3**, wherein step (b) is performed 1–2 times per day for about 7 days.

8. A kit for the treatment of vulvovaginal candidiasis consisting essentially of:

(a) a single dose of an effective amount of miconazole nitrate in a pharmaceutically acceptable carrier and in a form adapted to be administered intra-vaginally; and

(b) an amount of miconazole nitrate in a pharmaceutically acceptable carrier adapted to be applied topically to the vulva.

9. The kit of claim **8**, wherein the single dose of miconazole nitrate adapted to be administered intra-vaginally comprises about 400 to about 2000 mg of miconazole nitrate.

10. The kit of claim **8**, wherein the single dose of miconazole nitrate adapted to be administered intra-vaginally comprises about 600 to about 1200 mg of miconazole nitrate.

11. The kit of claim **8**, wherein the single dose of miconazole nitrate adapted to be administered intra-vaginally comprises 2.5 g of 16% miconazole nitrate cream, 5 g of 8% miconazole nitrate cream, 5 g 12% miconazole nitrate cream or 5 g 16% miconazole nitrate cream.

12. The kit of claim **8**, wherein the amount of miconazole nitrate in a pharmaceutically acceptable carrier adapted to be applied topically to the vulva is a sufficient amount to be applied 1–2 times per day for about 7 days.

13. The kit of claim **10**, wherein the amount of miconazole nitrate in a pharmaceutically acceptable carrier adapted to be applied topically to the vulva is a sufficient amount to be applied 1–2 times per day for about 7 days.

* * * * *