

Women's Self-reported Understanding of Labeling and Response to Over-the-Counter Miconazole for the Treatment of Self-diagnosed Vaginal Yeast Infections*

Gloria A. Bachmann, MD; Marianne T. Balay, MS, RN; Charles P. Wajszczuk, MD

Although previous studies suggest that women cannot reliably self-diagnose vulvovaginal candidiasis, findings from this study suggest that—in clinical terms—women who self-diagnose vaginal yeast infections and use OTC treatments experience a high degree of symptom relief and satisfaction.

STUDY SYNOPSIS

Among 4225 women who purchased an OTC antifungal treatment for self-diagnosed vulvovaginal candidiasis (VVC) symptoms, the majority understood the labeling and reported resolution of symptoms.

ABSTRACT

Objectives: Evaluate by telephone interview the self-reported understanding of package labeling information and treatment response in women who purchased an OTC antifungal intervention to treat self-diagnosed vulvovaginal candidiasis symptoms.

Study Design: Leaflets were placed in packages containing one miconazole vaginal Ovule Insert, 1200 mg plus 2% vulvar cream (OTC), inviting users to participate in a telephone interview.

Results: Among 4225 evaluable women, 75.5% appropriately fulfilled instructions for use and heeded warnings, precautions, and recommendations. Symptom improvement within 3 days was reported in 92.7% of women, with 89.3% reporting complete symptom relief by day 7, 96.8% reporting they understood directions on the outside of the package, and 96.6% report-

ing they understood the information on the consumer information leaflet inside the package.

Conclusions: The majority of women understood the labeling and warnings on the OTC miconazole vaginal insert, 1200 mg plus 2% vulvar cream, and reported resolution of their symptoms.

INTRODUCTION

Fifteen years ago, the first topical prescription drugs to treat symptoms of VVC were approved for OTC use by the FDA.¹ Over time, it became clear that although the information on these products was nearly identical, its organization and placement varied considerably. Therefore, in 1997 the FDA proposed a standardized labeling format to help women select and use these products more effectively.^{1,2}

This Phase IV survey evaluated self-reported respondent comprehension of labeling on an OTC product containing miconazole as well as each user's self-reported response to this intervention.

MATERIALS AND METHODS

The product labeling followed the FDA-approved Drug Facts³ labeling format. Women purchased the product at pharmacies and retail chain stores. Subject information was limited to printed directions on the box and the leaflet inside the package. An invitation to participate in the survey was placed inside the package and included a unique incentive reimbursement code (IRC) to prevent repeat participation.

Inclusion Criteria

Women aged 12 years and older called a toll-free telephone number to participate in the survey. They provided a valid IRC number, and it was confirmed that they could read and speak English. Minors required a

*This manuscript is the result of a nationwide survey of women in the United States.

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TABLE 1. Flowchart of Study Protocol

Procedure	Registration	Therapy Day 1	Postpurchase Follow-up	AE/SAE Follow-up, If Required
Users called, provided a valid IRC, completed registration survey, and scheduled the follow-up survey	X	X		
Interviewers gave subjects instructions on diary use				
Self-deselected subjects* called, provided a valid IRC, completed a registration survey, and then completed a follow-up survey				
Interviewers verified IRC				
Subjects used the product		X		
Interviewer conducted a CATI on VVC and risk factors, outcomes, and HCP interactions			X	
Subjects completed a follow-up survey			X	
Interviewer requested subject permission to contact the HCP for medical follow-up for AE and/or SAE. (subgroups)			X	X
Interviewer notified sponsor immediately of SAE for FDA reporting				X

*Self-deselected subjects did not use the product.
 AE = adverse event; CATI = computer-assisted telephone interview; HCP = health care provider; IRC = incentive reimbursement code; SAE = serious adverse event; VVC = vulvovaginal candidiasis.

parent or guardian to listen or participate in the telephone survey. There were no exclusion criteria.

Study Drug Use

The soft gelatin vaginal insert containing miconazole nitrate 1200 mg (marketed as the Monistat 1 Combination Pack) was self-administered intravaginally as a single dose. A small amount of the miconazole 2% vulvar cream was applied to the vulva, if needed, for external itching and relief of irritation.

Study Population

Subjects were deemed “evaluable” if they answered at least one question on the registration and follow-up surveys in addition to responding to the survey question: “Did you use the product?” The evaluable population was further classified into two groups—“self-select” and “self-deselect.” The “self-select” group used the product, whereas the “self-deselect” group did not use the product. Subjects were deemed “nonevaluable” if they failed to respond to at least one question on either survey.

Subjects younger than 18 years of age who chose not to participate in the survey and women who were terminated due to refusal to provide information regard-

ing their level of education were part of the nonevaluable population.

Study Procedures

Interviewers collected demographic and socioeconomic information from the subjects (Table 1). They determined if or when the product was used and scheduled the 7- to 15-day follow-up survey. If self-reported symptoms did not improve within 7 days, the women could consult a health care professional (HCP) to determine the correct diagnosis and treatment before completing the follow-up telephone survey. Women who did not use the product were asked to provide the reason for deselection and to complete the follow-up survey.

Use of Study Medication

As per the Drug Facts label, inappropriate product use was defined as the subject reporting:

- No previously diagnosed vaginal yeast infection
- At least three vaginal yeast infections in the past 6 months
- Pregnancy or breast-feeding
- Use of blood-thinning (anticoagulant) medication, or
- Baseline symptoms of lower abdominal pain, back

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TABLE 2. Demographic and Baseline Characteristics of Evaluable Subjects

Self-select Population (N = 4225)

	n	%*
Age (years)		
12-18	47	1.1
19-29	1306	30.9
30-39	1326	31.4
40-49	971	23.0
≥50	573	13.6
Refused	2	0.0
Race		
White	3054	72.3
Black	792	18.7
Hispanic	230	5.4
Native American	36	0.9
Asian/Pacific Islander	56	1.3
Other	45	1.1
Refused	12	0.3
Socioeconomic Status (annual income)		
<\$24,000	670	15.9
\$25,000-\$50,000	1561	36.9
\$51,000-\$75,000	915	21.7
>\$76,000	782	18.5
Refused	297	7.0
Education†		
<8th Grade	53	1.3
High School Graduate	848	20.1
Some College	1572	37.2
College Graduate	1268	30.0
At Least Some Graduate Training	484	11.5
Regular Health Care Provider		
No	497	11.8
Yes	3728	88.2

*Percentages are based on the number of consumers in each population. The "n" for categories may not sum to the total "N" due to missing data.
†Highest level of education achieved.

or shoulder pain, fever, chills, nausea, vomiting, rash, or foul-smelling vaginal discharge.

Women who did not report that they acted in accordance with the labeled instructions and warnings included those who said that they did not contact an HCP even though they had symptoms that did not improve in 3 days or completely resolve in 7 days. Other reasons for noncompliance that women reported included having at least one of the following symptoms with their self-reported vaginal yeast infection since using the product and not

contacting an HCP: lower abdominal pain, back or shoulder pain, fever, chills, nausea, vomiting, rash, hives, foul-smelling vaginal discharge, or other symptom(s).

RESULTS

Study Population

Among 5609 women enrolled in the study, 75.3% stated that they used the product, while 24.7% of women were nonevaluable because they failed to answer at least one question on the registration and follow-up surveys. The evaluable and nonevaluable groups had similar demographic and baseline characteristics. Table 2 shows characteristics of evaluable subjects.

The information printed on the back and on the leaflet inside the package was understood by 96.8% and 96.6% of women, respectively. Only about 2% of women reported that this information was confusing (Table 3). Most women (86.9%) reported recognizing that their symptoms were similar to past yeast infections. Symptoms the women reported included vulvovaginal itching (93.1%), burning (56.0%), and irritation/discomfort (41.0%). Vaginal discharge was reported by 68.0% of women. Most rated the severity of their symptoms as moderate.

Risk factors that the enrolled women reported are summarized in Table 4. All women who stated they had no risk factors and who were not required to take follow-up action after using the product because of self-reported symptom relief were considered to have used the product as instructed on the package labeling (n = 2673; 63.3%). When combined with the 516 (12.2%) women who reported at least one risk factor and who stated that they took the required follow-up action after product use, 75.5% of women used the product exactly as instructed.

The percentage of women who used the product in accordance with labeled instructions ranged between 71.8% (less than 8th grade education) and 80.1% (blacks). One exception was 51.1% in the 12- to 18-year age range (Figure).

In the self-select group (those who reported they used the product), 89.6% reported they had previously consulted an HCP at some time prior to participating in this survey because of yeast-infection-like symptoms. Most (67.9%) reported they had experienced one vaginal yeast infection in the 6 months prior to their current yeast infection. More than two yeast infections were reported by 9.6% of women, and 80.3% of these women consulted an HCP as recommended on the label due to their symptoms. Among the 19.7% of women with more than two episodes of yeast infec-

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TABLE 3. Women's Assessment of Product Labeling

Self-select Population (N = 4,225)

	n	%
Drug Facts on the back of the package		
Not confusing	4091	96.8
Confusing	85	2.0
Confusing sections of the Drug Facts*		
• Uses	22/85	25.9
• Warnings	7/85	8.2
• Directions	41/85	48.2
• Other information	25/85	29.4
Reason*		
• Confusing language	15/85	17.6
• Type too small	6/85	7.1
• Did not read them	15/85	17.6
• Other	55/85	64.7
Confusing directions on the inside consumer information leaflet*		
Not confusing	4083	96.6
Confusing	93	2.2
Confusing sections for the information leaflet*		
• Back	30/93	32.3
• Front	59/93	63.4
• Missing	4/93	4.3
Reason*		
• Confusing language	24/93	25.8
• Type too small	6/93	6.5
• Did not read them	7/93	7.5
• Other	59/93	63.4

*Subjects could have more than one response, and missing responses are not listed.

tion symptoms who did not contact an HCP, 47.5% did not feel the episode was sufficiently significant, 26.3% decided to self-treat, 11.3% felt it was not convenient, 5.0% did not consult an HCP due to cost, 1.3% did not feel it would help, and 17.5% did not consult an HCP for other reasons.

Miconazole Use and Treatment Response

Complete symptom relief was reported by 91.5% of women. Improvement in symptoms was reported by 92.7% of these women within 3 days after using the study medication. Complete symptom relief was reported by 89.3% by 7 days after using the study medication.

DISCUSSION

The majority of women reported that they understood the information and instructions provided

TABLE 4. Self-reported Risk Factors of Enrolled Women

Evaluable Population (N = 4,225)

	n	%
No previous vaginal yeast infections diagnosed by an HCP	463	11.0
History of frequent vaginal yeast infections (ie, 3 or more in 6 months)	406	9.6
Pregnant or breast-feeding	165	3.9
Taking blood-thinning medication (eg, warfarin)	22	0.5
≥1 baseline symptom(s) within the past 30 days with the current yeast infection*	87	2.1
One or more risk factors present	1060	25.1

*Lower abdominal pain, back or shoulder pain, fever, chills, nausea, vomiting, rash, foul-smelling vaginal discharge, or other symptoms.
HCP = health care provider.

with the packaging for the OTC miconazole vaginal insert product, 1200 mg plus 2% vulvar cream. The finding that 86.9% of women said that they recognized their symptoms as similar to past yeast infections suggests that women who use OTC interventions have a history of similar symptoms.⁴ However, in a recent study of women's ability to self-diagnose VVC, only 33.7% of 95 women who purchased OTC antifungal treatments for vaginal yeast infection had "pure" VVC when laboratory diagnosis of VVC was checked objectively.^{5,6} An additional 20.0% had VVC plus another type of vaginitis. Also, women with a prior diagnosis of VVC were not more likely to have VVC than women without a prior diagnosis of pure VVC, and reading the label did not improve the ability to properly diagnose VVC in that population.⁶ In that study, there was no mention of the specific products purchased. Therefore, it is not known whether the labeling on selected products or a single product might have influenced the findings, or whether this was a problem with all the OTC products used in that study.

The majority of women in the current study reported they used the product in accordance with the labeled instructions and warnings. Correct use of the product as self-reported was lowest (51.1%) among women in the 12- to 18-year age range. The product labeling was developed in accordance with the FDA's regulated Drug Facts labeling format

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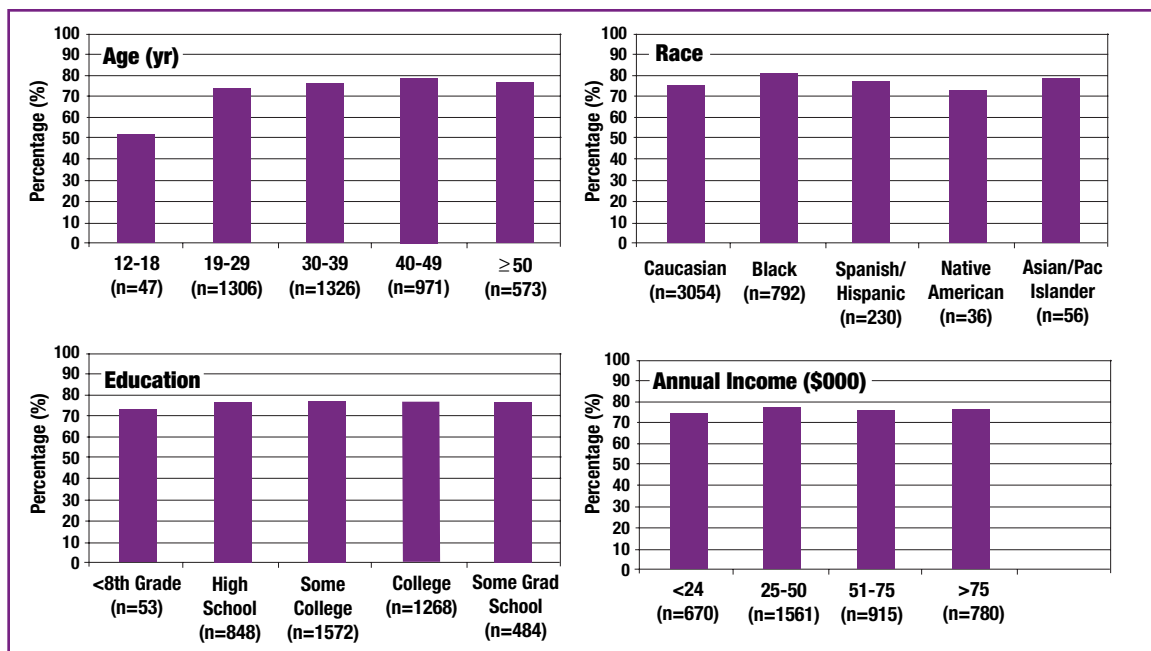


FIGURE. Percentage of women in four subgroups who reported using the OTC miconazole vaginal insert treatment in accordance with the labeled instructions and warnings.

for comprehension at a 6th-grade reading level, which includes this age group. Perhaps these young women are less familiar with the vaginal symptoms associated with VVC, and experience is important for using a product in accordance with instructions and warnings.

CONCLUSION

These results suggest that the majority of women believe that they understand the information and instructions that accompany the packaging of the vaginal insert product, miconazole 1200 mg plus 2% vulvar cream, used for self-diagnosed symptoms of VVC. Women reporting appropriate use also reported a satisfactory response to treatment, with 92.7% of women stating they experienced an improvement in symptoms by day 3 and 89.3% having complete relief of their symptoms by day 7.

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DISCLOSURE

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Corresponding author and reprint requests:

Gloria A. Bachmann, MD

125 Paterson Street, CAB

New Brunswick, NJ 08901

Phone: (732) 235-7633

Email: bachmaga@umdnj.edu.

Gloria A. Bachmann, MD, is Professor of Obstetrics and Gynecology and Medicine, University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, New Brunswick, NJ. **Marianne T. Balay, MS, RN**, is Assistant Vice President for Women's Health and Integrative Medicine Initiatives, Robert Wood Johnson University Hospital, New Brunswick, NJ. **Charles P. Wajszczyk, MD**, is Executive Director, Women's Health Research and Development, Johnson & Johnson Consumer and Personal Products, Skillman, NJ.

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