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Vulvovaginal candidiasis: A real-world evidence study of the perceived benefits of Canesten®

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Abstract

Objectives: Vulvovaginal candidiasis is common in women, causing discomfort and negatively impacting quality of life. Canesten® is an established over-the-counter brand. Its clotrimazole/fluconazole-based products, available in a variety of different formulations, have demonstrated efficacy and safety in the treatment of women with thrush/vaginal yeast infection in randomized trials. This real-world evidence study, conducted in the United Kingdom and Canada, aimed to provide consumer-important information on the benefits of Canesten, collecting retrospective information from consumers about their recent experience with the product.

Methods: Eligible participants were female, aged 18–60 years, and had experienced at least one episode of vaginal thrush (United Kingdom)/vaginal yeast infection (Canada) during the previous 6 months for which they had used at least one of the six Canesten products. Participants completed an online questionnaire eliciting information on the speed of onset of symptom relief, impact on quality of life, and product attributes/satisfaction.

Results: Over 90% of respondents reported improvements in symptoms and quality of life after starting treatment with a Canesten product. Improvements in symptoms within 4 h of the first time of use were perceived by 42% of consumers; 76%–88% reported symptomatic relief within 1 day. The perceived general speed of onset of symptomatic relief with a Canesten oral product (1–2 days) was slightly longer than that with a Canesten topical/intra-vaginal product (⩽1 day). Most users of Canesten single (90%) and dual product treatments (95%) reported that the products started to work from the first application. Women experiencing both internal and external symptoms of thrush/vaginal yeast infection reported Canesten dual product formulations to provide faster symptomatic relief than single product treatments. Over 90% of respondents were satisfied with their use of a Canesten product.

Conclusion: Canesten was found by consumers to offer rapid relief of the symptoms of thrush/vaginal yeast infection with improvements in quality of life. Consumer satisfaction was high.

Keywords

Women's health, candidiasis, real-world evidence, quality of life, efficacy, thrush

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Introduction

Most women (~70%) will experience vulvovaginal candidiasis (also known as thrush or vaginal yeast infection) at least once during their lifetime, most commonly during their childbearing years.[1,2] The causative pathogen in 85%–90% of cases is *Candida albicans*.[1,3] The disease may recur in up to half of all women, and rates of 8%–35% were reported for recurrent thrush/vaginal yeast infection (defined as four or more infectious episodes per year).[1,2,4] Symptoms of thrush/vaginal yeast infection include vaginal/vulvar itching, burning, redness, swelling, abnormal cottage cheese-like vaginal discharge, and soreness.[1,4] Thrush/vaginal yeast infection, especially when recurrent, can cause

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discomfort to and be upsetting for women, thus impacting their quality of life (QoL).[1,5]

Therapies recommended in current global guidelines for the management of women with thrush/vaginal yeast infection include topical/intra-vaginal (e.g. clotrimazole) or oral azoles (e.g. fluconazole).[6–9] Clotrimazole has long been used for the treatment of women with thrush/vaginal yeast infection – its use is supported by a wide evidence base.[10–14] Likewise, fluconazole has been shown to be effective in the treatment of women with thrush/vaginal yeast infection.[3]

Many women self-manage their symptoms.[5] Canesten® is an established over-the-counter (OTC) brand available in a variety of different formulations, containing either clotrimazole (internal and external creams, pessaries/vaginal tablets, and soft ovules) or fluconazole (oral capsules), which are designed to treat both the infection and the internal/external symptoms of thrush/vaginal yeast infection. Single products can be applied internally (intra-vaginal cream/intra-vaginal pessary) or externally (topical cream) to treat vaginitis or vulvitis, respectively (thus addressing all the symptoms of vulvovaginal candidiasis); other products combine two formulations/formats (e.g. an intra-vaginal pessary/tablet combined with external cream) and treat both vaginitis and vulvitis. Where a product treats vaginitis, it is treating the underlying cause of the infection. Overall, the product range provides women with a wide choice.

The efficacy and safety of Canesten products have been demonstrated in a number of randomized trials in women with thrush/vaginal yeast infection;[15–17] however, real-world data, providing patient insights on the routine use of these products, are lacking.

The primary aim of this real-world evidence study was to explore and identify the benefits of different product variants of Canesten (e.g. topical/intra-vaginal and oral treatments; single and dual product treatments) in the treatment of women who have experienced thrush/vaginal yeast infection, by collecting retrospective information from consumers about their recent experience with Canesten. The study focuses on the outcomes that are of particular importance to women with thrush/vaginal yeast infection: symptom improvement and relief, speed of onset of symptom relief, and QoL. Product attributes and satisfaction with Canesten were also assessed.

Methodology

Study design

This real-world evidence study was a retrospective observational study involving the collection of data through a computer-aided web quantitative interview. Canesten users in the United Kingdom and Canada were recruited from a consumer panel that had previously been profiled for thrush/vaginal yeast infection and had indicated that they were willing to complete online questionnaires of the type provided as part of this study. Consumers were informed electronically about the questionnaire, and those agreeing to take part were screened for eligibility using the preliminary questions of a computer-aided quantitative interview. Only those who met the inclusion criteria were eligible to complete the entire questionnaire (maximum duration ~20 min). Recruitment to the study was conducted by an independent agency, IQVIA Inc. Written informed consent was obtained from all subjects before the study.

According to the 'Governance arrangements for research ethics committees:2020 edition' document published by the NHS Health Resource Authority, UK, Section 2.3.15, 'Market research may be undertaken by professional market researchers, for example, for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the principles set out in the Market Research Society Code of Conduct or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review, except where otherwise required by law, for example, if it requires approval under the Mental Capacity Acts'. In line with BHBIA guidelines, in this study, participants were informed about the objective and use of the study prior to completing the questionnaire. As this study involved no randomization of participants, no intervention, no provision of the product to the consumers by Bayer or IQVIA, and no healthcare professional input or consultation of medical records, ethical approval or regulatory submission was not required.

Questionnaire development

Survey questions were developed on a pragmatic basis by Bayer AG and IQVIA. Questions were worded in a simple, consumer-friendly, self-exploratory, and non-technical manner. The content, phrasing, and order of the questions were reviewed prior to use by stakeholders associated with the project (Bayer AG and IQVIA employees) and amended as necessary. The questionnaire posed questions to consumers on:

- Demographics;
- Canesten usage patterns;
- Symptoms of thrush (in the United Kingdom)/vaginal yeast infection (in Canada) and the impact of such symptoms on their QoL;
- Experience with Canesten regarding symptom improvement, symptomatic relief, and QoL;
- Perceptions of the speed of onset of symptom relief with Canesten;
- Experience with specific Canesten product(s) used;
- Product attributes (e.g. ease of use); and
- Satisfaction with Canesten.

Questions relevant to the data presented are provided in Supplementary Figure 1.

Respondents selected answers to questions posed from a list provided. QoL was assessed using a 5-point Likert-type scale (1, *not at all*; 2, *a little*; 3, *some*; 4, *much*; 5, *very much*). Respondents were asked to rate the impact of their thrush/vaginal yeast infection symptoms on their everyday life/QoL before and after the use of a Canesten product using two questions: 'How much did the symptoms of vaginal thrush (in the United Kingdom)/vaginal yeast infection (in Canada) impair your everyday life before starting a treatment?' and 'Did your general QoL improve after you started to take a Canesten product?'. Whether Canesten was perceived as having improved symptoms of thrush/vaginal yeast infection was assessed using a 6-point scale (1, *strongly disagree*; 2, *disagree*; 3, *slightly disagree*; 4, *slightly agree*; 5, *agree*; 6, *strongly agree*).

Survey population

For inclusion in the study, participants had to be female, aged 18–60 years, have experienced at least one episode of vaginal thrush (United Kingdom)/vaginal yeast infection (Canada) during the previous 6 months (method of diagnosis was not queried), and to have used at least one of the Canesten products listed in Table 1 in the previous 6 months. Participants also needed to be able to read and understand the language of the online questionnaire (presented in English and French).

As this was a real-world data study, no exclusion criteria were specified.

Canesten products included in the questionnaire

The Canesten products investigated in the questionnaire were a mixture of single and dual product treatments, and topical/intra-vaginal and oral formulations (Table 1). Four are available in both the United Kingdom and Canada, marketed under different names (Canesten Thrush Pessary/Canesten Vaginal Tablet; Canesten Thrush Internal Cream/Canesten Vaginal Cream in Pre-filled Applicator; Canesten Thrush Oral Capsule/Canesoral Oral Capsule; and Canesten Thrush Combi Pessary & External Cream/Canesten Combi Pack Vaginal Tablet + External Cream). Two products are available only in the United Kingdom (Canesten Thrush Soft Gel Pessary and Canesten Thrush Combi Soft Gel Pessary & External Cream).

Data collection and analysis

Data were collected in the United Kingdom and Canada between the beginning of February and the end of March 2020. Responses to the online questionnaire were pseudo-anonymized and were forwarded directly to IQVIA electronically for data management and aggregated statistical analysis. Although the survey aimed primarily to collect data regarding the efficacy of Canesten products, respondents were also able to report details of any adverse events experienced through the Bayer website dedicated to spontaneous adverse event reporting. Any adverse event reported in this way was not linkable to a specific participant in the study.

Sample size and power

The estimated sample size was 400. This was based on the sample size usually used for market research tests ($n = 30$) multiplied by a factor of more than 10 to allow for the fact that the questionnaire was examining the retrospective experience of consumers who used the product within the previous 6 months. This sample size is supported by the calculation of the sample size using the Cochran formula, which is used to estimate the sample sizes for marketing surveys involving large populations and assumes an error margin of 5%, a standard deviation of 0.5, and a confidence level of 95%.[18] However, due to the real-world nature of the study, no limit was imposed on the number of participants who could be enrolled.

Statistical methods

Summary statistics only are presented. Data are provided as numbers and percentages, based on the total number of respondents, unless otherwise mentioned. Although data are reported for individual Canesten products, percentages are calculated based on the total users of those products.

Results

From a panel comprising 122,663 consumers profiled, 475 consented to participate, met the inclusion criteria, and completed the questionnaire: 262 from the United Kingdom and 213 from Canada.

Characteristics were generally similar between the United Kingdom and Canada respondents (Table 2). Overall, respondents were split relatively equally across three age groups: 18–30; 31–40; and 41–60 years. Most (61%) had experienced at least one episode of thrush/vaginal yeast infection over the past 6 months; however, recurrent thrush/vaginal yeast infection (defined in this study as ≥ 4 infectious episodes per year) was reported by 45% (117/262) of UK respondents and 32% (68/213) of Canadian respondents (Table 2).

Nearly one-third ($n = 141$, 30%) of respondents were taking Canesten for internal symptoms of thrush/vaginal yeast infection (vaginal soreness, burning, abnormal vaginal discharge, and white, cottage cheese-like discharge); 120 (25%) were taking Canesten for external symptoms (vulvar itching, redness); and 214 (45%) were taking Canesten for both internal and external symptoms. Most (70%) had used Canesten over the past 3 years or more (see Table 2).

Almost all ($n = 465$, 98%) respondents reported that their thrush/vaginal yeast infection impaired their daily life to

Table 1. Canesten products included in the questionnaire.

United Kingdom	Canada	Single or dual product treatment	Active ingredient	Mode of administration	Description
Canesten Thrush Pessary (500 mg pessary (clotrimazole))	Canesten Vaginal Tablet (200 mg vaginal tablet, 500 mg vaginal tablet (clotrimazole))	Single	Clotrimazole	Topical/intra-vaginal	A pessary/vaginal tablet to be inserted into the vagina
Canesten Thrush Internal Cream (10% w/w vaginal cream (clotrimazole))	Canesten Vaginal Cream in Pre-filled Applicator (10% w/w internal cream in a pre-filled applicator (clotrimazole))	Single	Clotrimazole	Topical/intra-vaginal	A vaginal cream in a pre-filled applicator for insertion into the vagina
Canesten Thrush Oral Capsule (150 mg capsule (fluconazole))	Canesoral Oral Capsule (150 mg capsule (fluconazole))	Single	Fluconazole	Oral	Oral capsule
Canesten Thrush Soft Gel Pessary (500 mg vaginal capsule (clotrimazole))	Not available	Single	Clotrimazole	Topical/intra-vaginal	A soft gel pessary to be inserted into the vagina
Canesten Thrush Combi Pessary & External Cream (500 mg vaginal capsule and 2% w/w cream (clotrimazole))	Canesten Combi Pack Vaginal Tablet + External Cream Two possible products: 1. Canesten 1 Day Combi 500 mg vaginal tablet + 1% w/w External Cream (clotrimazole) 2. Canesten 3 Day Combi 200 mg vaginal tablet + 1% w/w External Cream (clotrimazole)	Dual	Clotrimazole	Topical/intra-vaginal	A pessary/vaginal tablet to be inserted into the vagina plus an external cream for topical use
Canesten Thrush Combi Soft Gel Pessary and External Cream (500 mg vaginal capsule and 2% w/w cream (clotrimazole))	Not available	Dual	Clotrimazole	Topical/intra-vaginal	A soft gel pessary to be inserted into the vagina plus an external cream for topical use

some extent before starting treatment, with only 10 (2%) reporting that their symptoms had no impact.

The most commonly used Canesten product across both countries was Canesten Thrush Combi Pessary & External Cream/Canesten Combi Pack Vaginal Tablet + External Cream, which had been used by 45% of all respondents during the previous 6 months (see Table 2). A breakdown of Canesten product usage according to the number of episodes of thrush/vaginal yeast infection experienced over the previous 6 months is shown in Supplementary Figure 2. Overall, the proportion of respondents using each Canesten product increased in line with the number of thrush/vaginal yeast infection episodes experienced in the previous 6 months (up to four episodes).

Improvements in symptoms and QoL after starting Canesten were reported by 93% and 94% of users, respectively (see Figure 1(a) and (b)).

An improvement in symptoms within 4 h of the first use of a Canesten product was reported by 198 (42%) of consumers (Table 3). Most (26/41 (63%)) users of Canesten Thrush Soft Gel Pessary experienced an improvement in symptoms on the same day.

Most users of Canesten Thrush Pessary/Vaginal Tablet (96/123, 78%), Canesten Thrush Internal Cream/Canesten Vaginal Cream in Pre-filled Applicator (142/162, 88%), Canesten Thrush Soft Gel Pessary (31/41, 76%), Canesten Thrush Combi Pessary & External Cream/Canesten Combi Pack Vaginal Tablet + External Cream (181/213, 85%), and Canesten Thrush Combi Soft Gel Pessary and External Cream (37/44, 84%) reported symptom relief within a maximum of 1 day. Most users of Canesten Thrush Oral Capsule/Canesoral Oral Capsule (127/141, 90%) reported symptomatic relief within 1–2 days after application (Figure 2).

Among women using a single product treatment containing thrush internal cream, 116 of 123 (94%) using Canesten Thrush Pessary/Canesten Vaginal Tablet and 38/41 (93%) using Canesten Thrush Soft Gel Pessary (available in the United Kingdom only) reported itching and burning relief within 3 days of application. Among UK women using Canesten Thrush Internal Cream, 75 of 87

Table 2. Respondent characteristics.

Parameter	United Kingdom ($n=262$)	Canada ($n=213$)	Total ($n=475$)
Age group (years)			
18–30	94 (36)	54 (25)	148 (31)
31–40	93 (36)	81 (38)	174 (37)
41–60	75 (29)	78 (37)	153 (32)
Thrush/vaginal yeast infection in past 6 months (episode/s)			
1	145 (55)	145 (68)	290 (61)
2	89 (34)	51 (24)	140 (30)
2–4	24 (9)	15 (7)	39 (8)
>4	4 (2)	2 (1)	6 (1)
Canesten products used[a]			
Canesten Thrush Pessary/Canesten Vaginal Tablet	47 (18)	76 (36)	123 (26)
Canesten Thrush Internal Cream/Canesten Vaginal Cream in Pre-filled Applicator	87 (33)	75 (35)	162 (34)
Canesten Thrush Oral Capsule/Canesoral Oral Capsule	74 (28)	67 (32)	141 (30)
Canesten Thrush Soft Gel Pessary (available in the United Kingdom only)	41 (9)	–	41 (9)
Canesten Thrush Combi Pessary & External Cream/Canesten Combi Pack Vaginal Tablet + External Cream	112 (43)	101 (47)	213 (45)
Canesten Thrush Combi Soft Gel Pessary and External Cream (available in the United Kingdom only)	44 (9)	–	44 (9)
Had used Canesten previously	186 (71)	146 (69)	332 (70)

Data given as numbers (percentages); percentages do not total 100% in all cases due to rounding.
[a]Respondents could have used more than one Canesten product.

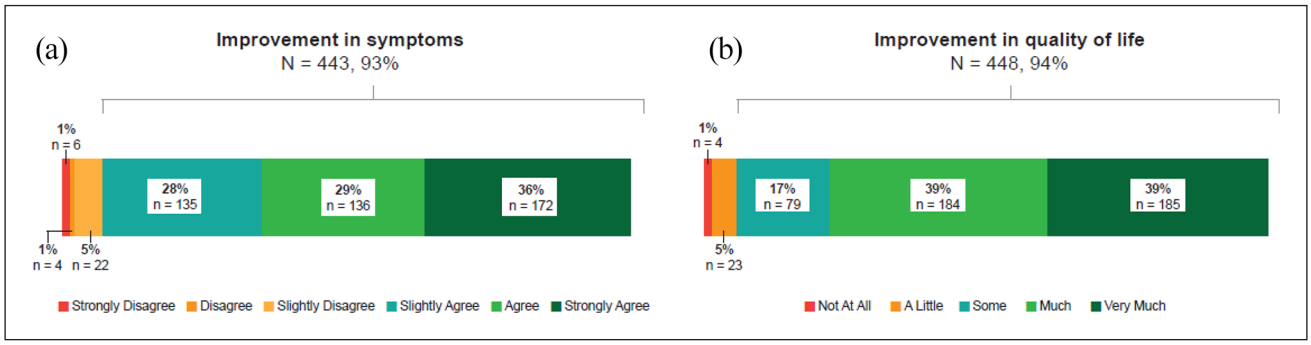

Figure 1. Consumer responses to questions asking whether Canesten had (a) relieved or improved symptoms of thrush/vaginal yeast infection and (b) improved QoL ($N=475$).

(86%) reported itching and burning relief up to and after 1 day of application.

Among users of Canesten dual product treatments, 189 of 213 (89%) who had used Canesten Thrush Combi Pessary & External Cream/Canesten Combi Pack Vaginal Tablet + External Cream and 41 of 44 (93%) who had used Canesten Thrush Combi Soft Gel Pessary and External Cream (available in the United Kingdom only) reported that the product provided itching and burning relief within 1 day of application.

Among 261 users of Canesten single product treatments and 243 users of Canesten dual product treatments, 90% and 95%, respectively, reported that the products started to work from a single application (Figure 3(a) and (b)). Of 34 women who had tried both single and dual product treatments (question asked to Canadian respondents only), 100% claimed that Canesten dual product treatment provided faster relief than the single product treatment Canesten Vaginal Tablet (Figure 3(c)).

A total of 184 (91%) of 201 UK users of Canesten Thrush Internal Cream agreed that Canesten as an internal cream provided a soothing effect, 12 (6%) of users were neutral and only 5 (2%) responded disagreed with this statement (Figure 4).

Among 84 respondents who had used products other than Canesten to treat a thrush/vaginal yeast infection episode, 48 (58%) stated that a Canesten product relieved their symptoms faster than these other products, 18 (21%) reported no difference, and 18 (21%) could not answer the question.

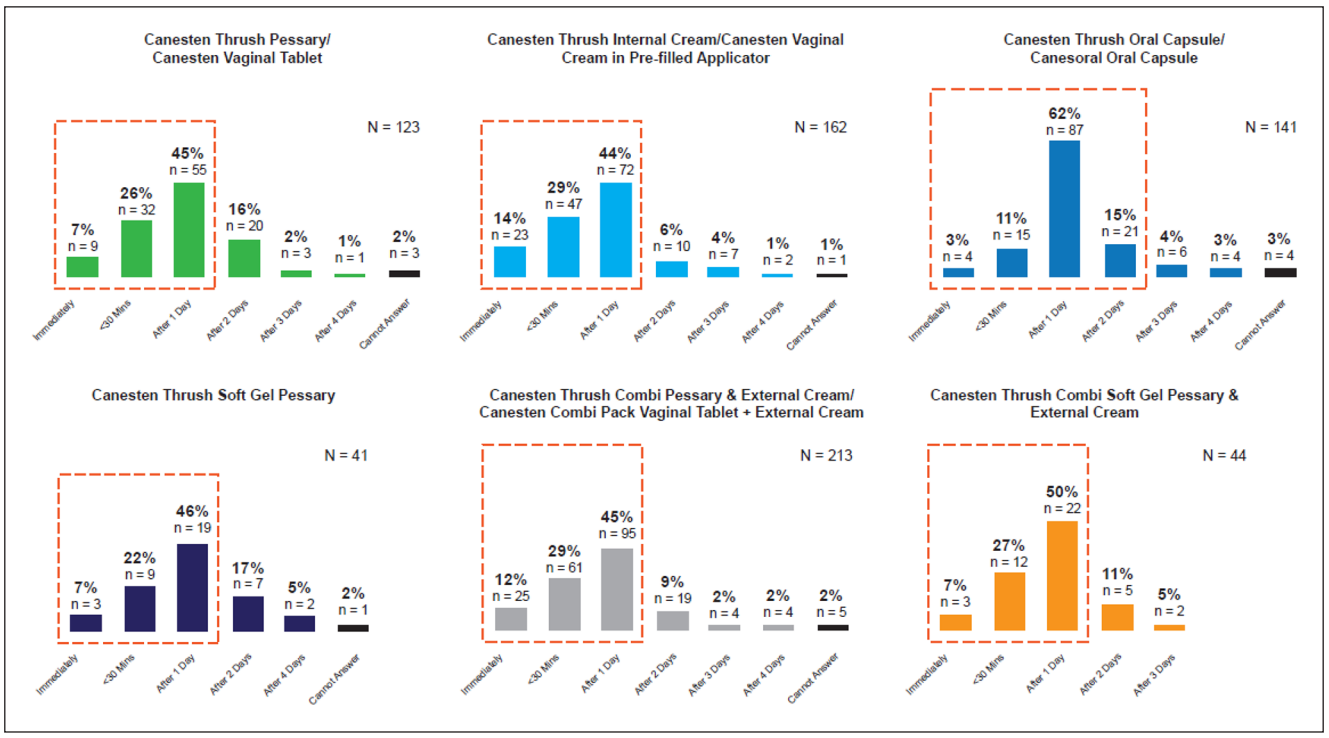

Figure 2. Time taken by Canesten products to provide symptomatic relief.

Table 3. Time to onset of symptomatic improvement after first use of a Canesten product.[a]

	Overall ($n=475$)	Canesten Thrush Pessary/ Canesten Vaginal Tablet ($n=123$)	Canesten Thrush Internal Cream/Canesten Vaginal Cream in Pre-filled Applicator ($n=162$)	Canesten Thrush Oral Capsule/ Canesoral Oral Capsule ($n=141$)	Canesten Thrush Combi Pessary & External Cream/ Canesten Combi Pack Vaginal Tablet + External Cream ($n=213$)	Canesten Thrush Soft Gel Pessary (available in the United Kingdom only) ($n=41$)	Canesten Thrush Combi Soft Gel Pessary and External Cream (available in the United Kingdom only) ($n=44$)
Within 4 h	198 (42)	61 (50)	78 (48)	53 (36)	101 (47)	14 (34)	18 (41)
After 4 h on same day	73 (15)	16 (13)	18 (11)	20 (14)	32 (15)	12 (29)	6 (14)
After 1 day	128 (27)	28 (23)	40 (25)	40 (28)	50 (23)	8 (20)	14 (32)
After 2 days	43 (9)	11 (9)	10 (6)	15 (11)	18 (8)	4 (10)	4 (9)
After 3 days	15 (3)	4 (3)	8 (5)	7 (5)	8 (4)	3 (7)	2 (5)
After 4 days	6 (1)	1 (<1)	3 (2)	4 (3)	0	0	0
After 5 days	2 (<1)	1 (<1)	2 (1)	0	0	0	0
After 6 days	2 (<1)	0	1 (<1)	1 (<1)	0	0	0
Within 1 week	6 (1)	1 (<1)	1 (<1)	0	4 (2)	0	0
No effect after 7 days	2 (<1)	0	1 (<1)	1 (<1)	0	0	0

Data given as numbers (percentages); percentages do not total 100% in all cases due to rounding.
[a]Respondents could have used more than one Canesten product.

A total of 431 (91%) consumers expressed satisfaction with a Canesten product for the treatment of thrush/vaginal yeast infection; 396 (83%), 341 (72%), and 326 (69%) of consumers agreed that they felt comfortable, fresh and clean, and confident, respectively, after using a Canesten product. More than 90% of consumers reported that they would use a Canesten product again ($n=440$, 93%) and would recommend Canesten to other women suffering from thrush/vaginal yeast infection ($n=441$, 93%). More than 80% ($n=398$, 84%) of consumers considered Canesten products for the treatment of thrush/vaginal yeast infection to be good value for money (Table 4). Canesten products were reported easy or very easy to use by 383 (81%) respondents, acceptable by 87 (18%), and difficult/very difficult by 5 (1%).

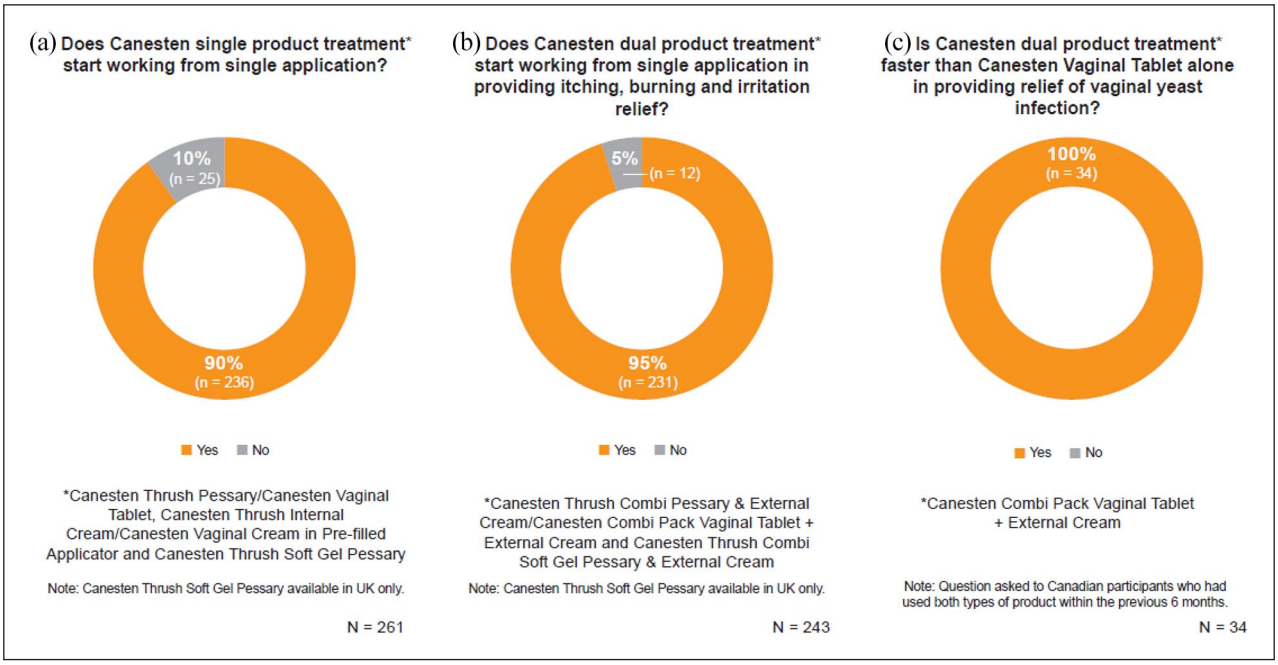

Figure 3. Time taken by Canesten products to start working from the first application with single (a) and dual (b) product treatments, and patients experiencing faster relief with dual versus single product treatments (c).

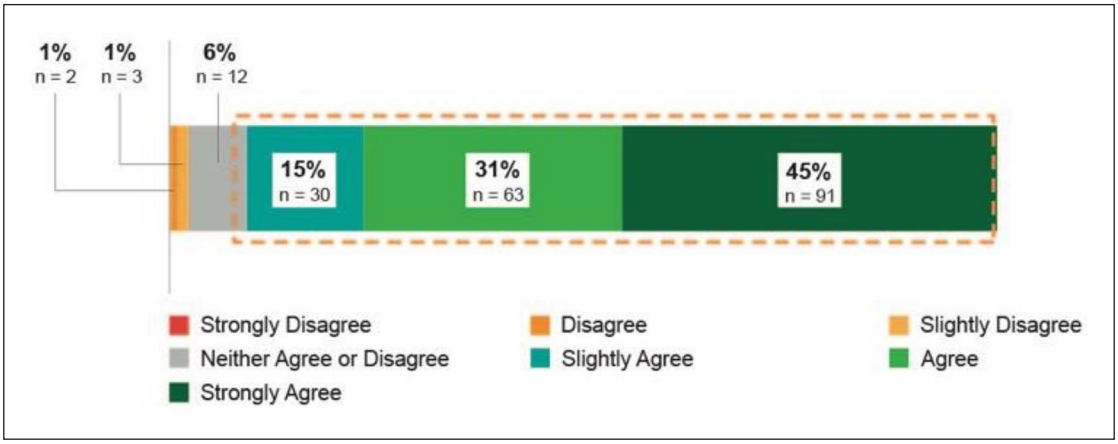

Figure 4. Consumer responses to a question asking whether Canesten Thrush Internal Cream provided a soothing effect ($N = 201$).

Table 4. Participants' responses ('Strongly agree'/'Agree'/'Slightly agree') to questions concerning satisfaction with Canesten products ($N = 475$).

	Strongly disagree	Disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Agree	Strongly agree
I am satisfied with Canesten	1 (<1)	4 (1)	20 (4)	19 (4)	47 (10)	147 (31)	237 (50)
I would recommend Canesten to other women	0	4 (1)	5 (1)	25 (5)	31 (7)	117 (25)	293 (62)
I would use a Canesten product again	1 (<1)	5 (1)	7 (2)	22 (5)	30 (6)	105 (22)	305 (64)
Canesten products for the treatment of thrush/ vaginal yeast infection are good value for money	4 (<1)	5 (1)	21 (4)	47 (10)	80 (17)	163 (34)	155 (33)
I felt comfortable after using a Canesten product	3 (<1)	3 (0.6)	22 (5)	51 (11)	97 (20)	187 (39)	112 (24)
I felt confident after using a Canesten product	6 (1)	7 (2)	25 (5)	111 (23)	91 (19)	141 (30)	94 (20)
I felt fresh and clean after using a Canesten product	6 (1)	9 (2)	42 (9)	77 (16)	113 (24)	134 (28)	94 (20)

Data given as numbers (percentages); percentages do not total 100% in all cases due to rounding.

Canesten Thrush Soft Gel Pessary was reported to be comfortable to insert and mess free by, respectively, 60/76 (79%) and 58/76 (76%) UK users of Canesten Thrush Soft Gel Pessary.

Discussion

This is the first retrospective real-world data study to examine experience with a wide range of OTC Canesten products in women who have experienced thrush/vaginal yeast infection and, as such, provides consumer-important information that adds supplementary value to data obtained from randomized trials. Randomized trials aim to examine the effect of thrush/vaginal yeast infection therapies on outcomes, such as clinical cure rate (i.e. complete resolution of symptoms of thrush/vaginal yeast infection) and/or mycological cure rate (a negative *Candida* culture).[3,10] The findings of the questionnaire used in this study, however, reveal not only that administration of a Canesten product improves symptoms of thrush/vaginal yeast infection in over 90% of users but also highlights the rapid speed of onset of Canesten products for the symptomatic relief of thrush/vaginal yeast infection, with 42% of consumers perceiving an improvement in associated symptoms within 4 h, and over 75% reporting relief of symptoms within 1 day after taking a Canesten product.

Topical agents are known to relieve the symptoms of vulvovaginal candidiasis more rapidly than oral agents.[19] As expected, therefore, respondents perceived the general speed of onset of symptomatic relief with Canesten Thrush Oral Capsule/Canesoral Oral Capsule (1–2 days) to be slightly slower than that of each of the Canesten topical/intra-vaginal products assessed (up to 1 day). Although topical/intra-vaginal and oral agents are perceived to have equivalent efficacy,[3] many women prefer the convenience of oral therapy over the application of creams or pessaries despite the slower onset of action of oral agents.[19]

The majority of users of Canesten single (90%) and dual product treatments (95%) reported that the products started to work from the first application. However, respondents who had tried both considered that symptom relief with dual products was generally faster. Women experiencing both internal and external symptoms of thrush/vaginal yeast infection (e.g. itching and burning) reported Canesten dual product formulations to provide faster relief of symptoms than single product treatments.

In addition to providing information on the speed of onset and symptom relief of various Canesten products, the findings of the study questionnaire also add to the limited data currently available concerning the QoL of women with thrush/vaginal yeast infection. The few published data available indicate that thrush/vaginal yeast infection, especially when recurrent, can cause discomfort and notably impact the quality of women's lives.[1,5,20] According to our findings, 98% of respondents, many of whom would not be classed as having recurrent disease, reported that symptoms negatively impacted their QoL to some extent prior to treatment with a Canesten product. Likewise, few studies have explored the QoL of women after receiving treatment for thrush/vaginal yeast infection, but our finding that 94% of respondents in this survey reported an improvement in QoL after starting to take a Canesten product is in line with that of another study reporting a similar improvement in women with chronic vulvovaginal candidiasis following effective treatment with fluconazole.[21]

More than 90% of respondents were satisfied with their use of a Canesten product to treat thrush/vaginal yeast infection and would recommend the product to other women with thrush/vaginal yeast infection. Most consumers (70%) had used a Canesten product in the past 3 years or more and 93% reported that they would use Canesten products again. These results are not surprising, given the relative rapidity of perceived effect after starting treatment with a Canesten product ($>$ 90% reported symptom relief within 1–2 days of taking the product).

The strengths of this study include the large sample size and the fact that it provides real-world experience of Canesten product use. Real-world data relate to the routine use of a product/intervention within the context of a self-care setting; hence, the data generated differ from, and complement, those provided under the well-controlled conditions of a randomized trial. Real-world data provide important patient insights on how a product works in a real-life setting, reflecting actual use in practice and free from the specific limitations of a randomized trial. In this way, such data bridge the efficacy/effectiveness gap between how a product performs in a randomized trial versus its performance in a real-life setting. To date, the only similar real-world study published in this disease area has been a prospective study, conducted in Germany, examining the efficacy and tolerability of Canesten products in women with vulvovaginal mycoses being treated by a gynecologist.[22] In the current real-world data study, consumers opted to take (and bought) Canesten products themselves (no third-party intervention or prescription was involved/required), so the self-reported results may be considered as neutral and unbiased.

Limitations of the study include the methodology: currently no guidance exists regarding the studies that use online questionnaires to collect data. Although not formally validated, questionnaires, similar to the one used in this study, have previously been used to obtain consumer experience with Canesten products, as in the aforementioned prospective real-world study exploring the efficacy and tolerability of Canesten in women with vulvovaginal mycoses.[22] The data collected in the current real-world study were retrospective in nature and, hence, not as robust as those obtained in prospective studies or clinical trials. To reduce the recall bias inherent in a retrospective study,[23] respondents in the current study were required to have used Canesten within the previous 6 months. Post hoc analysis of our data also revealed that

of the 332 experienced Canesten users (i.e. those who had used a Canesten product to treat thrush/vaginal yeast infection within the past 3 years) who participated in the survey (70% of the overall population), 235 (71%) reported that they had used the product within the previous 3 months (Bayer data on file). Hence, the potential for recall bias in our findings is limited. Finally, respondents were selected from a consumer panel comprising people who were willing to complete online questionnaires and who were informed of the objective and use of the study; hence, the findings could be subject to reporting and selection bias. Although such panels are generally considered representative of the general population, those who completed the questionnaire had used Canesten products within the previous 6 months and may not, therefore, represent all patients with thrush/vaginal yeast infection in the United Kingdom and Canadian general populations.

Conclusion

This real-world data study of the United Kingdom and Canada Canesten product users demonstrated that Canesten in a wide range of formulations/products offers rapid relief of the symptoms of thrush/vaginal yeast infection with improvements in QoL. Canesten was associated with a high level of consumer satisfaction. The information provided by respondents on a wide range of Canesten products means that the study findings will help consumers to navigate the Canesten clotrimazole/fluconazole product range.

Despite the limitations of the study, we consider our findings to be robust and to add supplementary value to the information obtained from randomized trials of thrush/vaginal yeast infection therapies. Further real-world data studies of Canesten use in women with thrush/vaginal yeast infection would be of interest.

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Data availability

Data generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: L.Z., R.d.S., A.E., and S.T. are employees of Bayer Consumer Care AG, Switzerland. K.Y. is an employee of Bayer Public Limited Company, UK. L.Z., R.d.S., and A.E. were responsible for the study concept and design; L.Z., R.d.S., A.E., S.T., and K.Y. were responsible for analysis and interpretation of the data, and the drafting and critical review of the article, and approving the final version of the article. All authors agree to be accountable for all aspects of the work and in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethical approval

According to the 'Governance arrangements for research ethics committees:2020 edition' document published by the NHS Health Resource Authority, UK, Section 2.3.15 (linked here), 'Market research may be undertaken by professional market researchers, for example, for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the principles set out in the Market Research Society Code of Conduct or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review, except where otherwise required by law, for example, if it requires approval under the Mental Capacity Acts'. In line with BHBIA guidelines, in this study, participants were informed about the objective and use of the study prior to completing the questionnaire. As this study involved no randomization of participants, no intervention, no provision of the product to the consumers by Bayer or IQVIA, and no healthcare professional input or consultation of medical records, ethical approval or regulatory submission was not required.

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Informed consent

Written informed consent was obtained from all subjects before the study.

Supplemental material

Supplemental material for this article is available online.

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