

**Zero Candida Ltd.**

**Market analysis**

**February 2025**



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## Executive Summary

**The global** vulvovaginal candidiasis treatment market size was valued at USD 1,423 million in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 5.25% from 2024 to 2030, reaching USD 2,037.09 million and a compound annual growth rate (CAGR) of 4.4% from 2024 to 2033.

The rising prevalence of Vulvovaginal Candidiasis among women, increasing risk of recurrent Vulvovaginal Candidiasis, driving the demand for new therapeutics for treatment, augmenting the Vulvovaginal Candidiasis treatment market's growth. In addition, the growing awareness of candidiasis infection among the target population and rising product innovation across the world to cure candidiasis are expected to be the further factors driving the demand for new therapeutics.

Up to 75% of women will have at least one vaginal yeast infection in their life<sup>1</sup>. Moreover, recurrent VVC (Vulvovaginal Candidiasis) affects nearly 8% of women globally (for women above the ages of 15-60).

Recurrent VVC is defined as having more than 4 episodes of VVC. According to the data above, 100% of women with Recurrent VVC will purchase a combination of over-the-counter and prescription antifungal treatments, usually with the common use of oral agents. Compared to women with non-recurrent VVC, 55.2% will purchase prescription antifungal treatment, 37% over-the-counter antifungal, 5.6% will purchase a combination of both treatments, and the rest will not purchase any treatment.

North America dominated the global industry in 2023 and accounted for the maximum share of more than 40% of the overall revenue. The region is expected to expand further at a steady growth rate, maintaining its dominant position throughout the forecast period. This dominance can be attributed to the high disease prevalence, the rise in patient awareness, increased healthcare expenditure, and the presence of major players in the region.

**The US market** dominated the North America Vulvovaginal Candidiasis Treatment Market by Country in 2023; thereby, achieving a market value of \$345 million by 2028. **The Canada market** is experiencing a CAGR of 6.3% during (2022-2028).

The U.S. is expected to lead the regional market by 2030 due to increasing research and product development activities, increasing patient population, governmental initiatives to raise awareness of the conditions, etc. According to the MMR analysis, around 149,934 women in the United States were diagnosed with Vulvovaginal Candidiasis (VVC) in April 2023, with 3.4% of them experiencing recurrent VVC (RVVC).

**The European** vulvovaginal Candidiasis Treatment Market will grow at a 4.2% CAGR during the forecast period (2022-2028). Europe is one of the top regions driving vulvovaginal candidiasis treatment demand, and prospects are being boosted by the presence of a well-developed healthcare infrastructure and the availability of skilled medical staff. Europe's market is expected to grow at a robust rate; the region invests in biopharmaceutical

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<sup>1</sup> <https://my.clevelandclinic.org/health/diseases/5019-vaginal-yeast-infection>

research and development to develop cures for uncommon diseases, which bodes well for vulvovaginal candidiasis treatment system providers in the region.

- **In the U.S.**, the number of women between the ages of 15-60 is approximately 105 million. Therefore, an estimated 8,400,000 women will suffer from Recurrent VVC.
- **In Canada**, the number of women between the ages of 15 and 60 is approximately 12 million. Therefore, an estimated 961,800 women will suffer from Recurrent VVC.
- **In Europe**, the number of women between the ages of 15 and 60 is approximately 215 million; therefore, an estimated 17,200,000 women will suffer from Recurrent VVC.

In conclusion, the vulvovaginal candidiasis treatment market is a fast-growing market, effected by the increasing prevalence, growing awareness and high demands. The market has an estimation of reaching over USD 2 billion by 2030, with a compound annual growth rate of 5.25% globally and 3.9% in North America and 4.2% in Europe.

## Candidiasis

Candidiasis is a fungal infection caused by a yeast (a type of fungus) called *Candida*<sup>2</sup>. Some species of *Candida* can cause infection in people; the most common is *Candida albicans*. *Candida* normally lives on the skin and inside the body, such as the mouth, throat, gut, and vagina, without causing problems. *Candida* can cause infections if it grows out of control or enters deep into the body. For example, it can cause infections in the bloodstream or internal organs like the kidney, heart, or brain.

Candidiasis route	Avg. Incidence	Approx. Target population	Approx. Individuals Impacted
Invasive	0.01%	7,800,000,000	702,000
Oropharyngeal	-	-	15,337,200
HIV/AIDS	72.50%	15,200,000	11,020,000
Head/neck cancer	40%	650,000	260,000
Is Organ transplant	11.60%	100,800	11,690
Infants	6%	67,425,000	4,045,500
<b>Recurrent vulvovaginal</b>	<b>8%</b>	<b>1,682,200,000</b>	<b>134,560,000</b>

Source: "Vulvovaginal Candidiasis: A Current Understanding and Burning Question"

## Vaginal Candidiasis

*Candida* can cause an infection if conditions change inside the vagina to encourage its growth<sup>3</sup>. Things like hormones, medicines, or changes in the immune system can make infection more likely. The common term for candidiasis in the vagina is a vaginal yeast infection. Other names for this infection are vaginal candidiasis, vulvovaginal candidiasis, or candidal vaginitis.

Candidal vulvovaginitis occurs when *Candida* species superficially penetrate the mucosal lining of the vagina and causes an inflammatory response. The dominant inflammatory cells are typically polymorphonuclear cells and macrophages. The inflammatory response results in copious thick discharge and vaginal irritation, excoriations, dysuria, itching, burning, dyspareunia, or swelling.

The symptoms of vaginal candidiasis include Vaginal itching or soreness, Pain during sexual intercourse, Pain or discomfort when urinating, and Abnormal vaginal discharge. Vaginal candidiasis is often mild. However, some women can develop severe infections involving redness, swelling, and cracks in the wall of the vagina.

Recognized risk factors for acute candidal vulvovaginitis include estrogen use, elevated endogenous estrogens (e.g., pregnancy or obesity), diabetes mellitus, immunosuppression (i.e., chemotherapy or antimetabolite medications, HIV infection, or transplant patients), and broad-spectrum antibiotic use. Although candidal vulvovaginitis is more common in sexually active women, evidence that candidal infection is sexually transmitted

<sup>2</sup> <https://www.cdc.gov/fungal/diseases/candidiasis/>

<sup>3</sup> <https://www.cdc.gov/fungal/diseases/candidiasis/genital/>

is lacking. Patients with recurrent candidal vulvovaginitis, defined as 4 or more episodes of culture-proven candidal vulvovaginitis, have predisposing genetic factors that cause them to be susceptible to recurrent fungal infections. These factors may also cause a predisposition to Candida hypersensitivity reactions.

Up to 75% of women will have at least one vaginal yeast infection in their life<sup>4</sup>, Moreover, recurrent VVC (Vulvovaginal Candidiasis) affects nearly 8% of women globally<sup>5</sup>.

Despite appropriate treatment, recurrence is relatively common and is estimated to range from 14% to 28% in otherwise healthy individuals. Most often, recurrent disease arises from persistent vaginal organisms or endogenous reinfection with an identical strain of *Candida*. Less commonly, the disease may result from a new strain of *Candida*. Recurrent disease may be triggered by antibiotic use, sexual activity, or dietary factors. Genetic susceptibility may also affect a person's risk for recurrent disease.

The most common responsible pathogen is *C.albicans*, accounting for 90% of cases, with most of the remaining cases caused by *Candida glabrata*<sup>6</sup>.

	All females		VVC In past year		Over-the counter antigungal treatment		Prescription antigungal tretment	
	Weighted n	%	Weighted n	%	Weighted n	%	Weighted n	%
Total	1869		98	5.20%	39	40%	71	72.20%
18-29	349	18.70%	16	16.70%	9	22%	13	18.90%
30-44	469	25.10%	33	34.10%	15	39%	24	34.20%
45-59	472	25.30%	23	23.20%	10	24%	10	14.30%
>60	579	31%	26	26.00%	6	14%	23	32.70%

Source: "Survey of incidence, lifetime prevalence, and treatment of self-reported vulvovaginal candidiasis, United States, 2020".

Because over-the-counter treatments are widely available, candidal vulvovaginitis is under-reported; therefore, detailed epidemiological data for this disease process is unavailable. Furthermore, diagnosis is based on both clinical and ancillary evaluation.

As a result, epidemiologic reports based on culture alone, in which 10% of asymptomatic women have positive candidal cultures, overestimate the disease incidence. Furthermore, studies demonstrate that because self-diagnosis is inaccurate, data derived from patient queries is also imprecise.

**Worldwide, recurrent vulvovaginal candidiasis affects about 138 million women annually (range 103-172 million), with a global annual prevalence of 3,871 per 100,000 women; 372 million women are affected by**

4 <https://my.clevelandclinic.org/health/diseases/5019-vaginal-yeast-infection>

5 <https://pmc.ncbi.nlm.nih.gov/articles/PMC7151053/>

6 <https://www.ncbi.nlm.nih.gov/books/NBK459317/>

**recurrent vulvovaginal candidiasis over their lifetime. The 25-34 year age group has the highest prevalence (9%).**

By 2030, the population of women with recurrent vulvovaginal candidiasis each year is estimated to increase to almost 158 million, resulting in 20,240,664 extra cases with current trends using base case estimates in parallel with an estimated growth in females from 3.34 billion to 4.181 billion. In high-income countries, the economic burden from lost productivity could be up to US\$14.39 billion annually. The high prevalence, substantial morbidity, and economic losses of recurrent vulvovaginal candidiasis require better solutions and improved quality of care for affected women<sup>7</sup>.

### Evaluation

Diagnostic studies utilized to confirm the presence of *Candida* include 10% potassium hydroxide (KOH) and wet mount smears of the vaginal discharge for microscopy, pH testing, and potentially fungal culture or commercial polymerase chain reaction (PCR) tests.

In patients with vulvovaginal candidiasis, the vaginal pH is typically below 5. Characteristic findings of vaginal candidiasis include the prominence of lactobacillus bacteria and inflammatory cells on wet prep, a negative Whiff test (i.e., no fishy odor with the application of KOH to the slide), and budding yeast, hyphae, or pseudohyphae on microscopy, which are typically seen most easily on the KOH prep. Microscopy and pH testing can also identify clue cells, indicating bacterial vaginosis, and trichomonads, indicating trichomoniasis, which should be ruled out (or diagnosed) concurrently<sup>8</sup>.

Most infections are secondary to *Candida albicans*; therefore, consistent microscopy findings in the clinical setting of a reproductive-age woman with vulvovaginitis and confirmatory cultures for *Candida* are unnecessary. Cultures should be considered in patients with recurrent disease and patients with a negative work-up in the setting of symptoms consistent with vulvovaginal candidiasis. However, if cultures cannot be performed, empiric treatment is reasonable.

Because *Candida* species are part of normal vaginal flora in many women, routine cultures in asymptomatic women are discouraged.

### Treatment

Candida infections are treated with antifungal medications such as nystatin, clotrimazole, amphotericin B, and miconazole<sup>9</sup>. Mild or moderate genital Candida infections can have treatment with antifungal vaginal cream. The

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<sup>7</sup> <https://pubmed.ncbi.nlm.nih.gov/30078662/>

<sup>8</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC6357464/>

<sup>9</sup> <https://www.ncbi.nlm.nih.gov/books/NBK560624/>



antifungal creams come in 1, 3, or 7-day treatment. Econazole or fluconazole 150 mg orally one-time dose can also be prescribed.

Oral and topical treatments have similar efficacy, but oral medications are more expensive. Clinicians should avoid prescribing fluconazole in the first trimester of pregnancy. For recurrent vaginal candida infections, fluconazole dosing is on days 1, 4, and 7 and then weekly for six months is given. A similar treatment can be used for oral thrush, with oral lozenges as a substitute dose form. Systemic candidiasis requires treatment with oral or intravenous antifungal medications, including caspofungin, fluconazole, and amphotericin B.

In cases of denture stomatitis, the patient should refrain from using their denture for at least two weeks, along with the topical application of antifungal medication. Angular cheilitis occurs due to loss of vertical dimension. Thus, after the infection subsides, the fabrication of new denture prostheses with proper vertical dimensions is essential. Oral application of probiotics can serve as an adjuvant in treating oral candidiasis.

For complicated candidal vulvovaginitis, including patients who are immunosuppressed or have a recurrent infection, extended treatment regimens are commonly utilized, such as intravaginal azole therapy for at least 1 week or oral treatment with fluconazole 150 mg (renally adjusted for CrCl <50 ml/min) once every 3 days for 3 doses. Patients with recurrent candidal vulvovaginitis may benefit from suppressive therapy with weekly oral fluconazole for 6 months. However, pregnant patients should not be given oral antifungals. In these patients, a 7-day course of intravaginal treatment is recommended. Fluconazole is considered safe in breastfeeding women.<sup>10</sup> Nonpharmacologic therapies (e.g., intravaginal or oral yogurt therapy, intravaginal garlic, or douching) have not been found to be effective.

	1 Episode		2 Episode		3 Episode		4-5 Episode	
	Weighted n	%	Weighted n	%	Weighted n	%	Weighted n	%
Over-the counter antifungal only	22	37%	0	0.00%	1	0%	0	0.00%
Prescription antifungal only	34	55.20%	18	76.40%	3	76%	0	0.00%
Over the counter and prescription antifungal	3	5.60%	5	23.60%	2	24%	5	100.00%
Alternative/nonmedicinal treatment	0	0.00%	0	0.00%	1	0%	0	0.00%
No treatment	2	3%	0	0.00%	1	0%	0	0.00%

Source: "Survey of incidence, lifetime prevalence, and treatment of self-reported vulvovaginal candidiasis, United States, 2020".

<sup>10</sup> <https://pubmed.ncbi.nlm.nih.gov/28164373/>



## The Vulvovaginal Candidiasis Treatment Market

The global vulvovaginal candidiasis treatment market size was valued at USD 1,423.82 million in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 5.25% from 2024 to 2030, reaching USD 2,037.09 million<sup>11,12,13</sup>, and a compound annual growth rate (CAGR) of 4.4% from 2024 to 2033<sup>14</sup>.

The rising prevalence of Vulvovaginal Candidiasis among women, increasing risk of recurrent Vulvovaginal Candidiasis, driving the demand for new therapeutics for treatment, augmenting the Vulvovaginal Candidiasis treatment market's growth. In addition, the growing awareness of candidiasis infection among the target population and rising product innovation across the world to cure candidiasis are expected to be the further factors driving the demand for new therapeutics.

For instance, in September 2021, Cidara Therapeutics, Inc. presented new clinical and non-clinical data for its Rezafungin, which is being developed for both the treatment and prevention of serious fungal infections, such as candidemia and invasive candidiasis. Hence, such product innovation is expected to boost the growth of the Vulvovaginal Candidiasis treatment market.

The increasing demand for vulvovaginal candidiasis treatment can be attributed to several key factors driving its growth. Firstly, there has been notable progress in the development of new antifungal medications, coupled with a significant rise in healthcare expenditure worldwide<sup>15</sup>.

Furthermore, the global population's growing awareness of the need for effective yet cost-efficient treatment options, particularly among the elderly demographic, has led to a surge in demand for vulvovaginal candidiasis treatment on a global scale.

Additionally, the escalating prevalence of chronic diseases such as cancer, cardiovascular ailments, neurological disorders, and diabetes on a global scale is anticipated to further boost the demand for vulvovaginal candidiasis treatment, driving market growth through the year 2028. Moreover, increasing awareness about the importance of hygiene and the advantages of adopting new, cost-effective treatment options is expected to provide additional support to the vulvovaginal candidiasis treatment market during the forecast period.

The growing use of broad-spectrum antibiotics, such as Fluconazole, to combat yeast infections is projected to contribute to the increased demand for vulvovaginal candidiasis treatment, thereby fostering market growth. Vaginal candidiasis ranks as the second most common type of vaginal infection in the United States, following bacterial vaginal infections, with an estimated 1.4 million outpatient visits for vaginal candidiasis annually.

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11 <https://www.maximizemarketresearch.com/market-report/vulvovaginal-candidiasis-treatment-market/190604/>

12 <https://www.grandviewresearch.com/industry-analysis/vulvovaginal-candidiasis-treatment-market-report#>

13 <https://www.futuremarketinsights.com/reports/vulvovaginal-candidiasis-treatment-market>

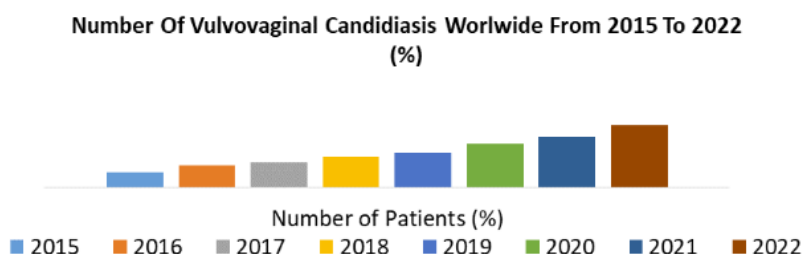
14 <https://www.alliedmarketresearch.com/drugs-for-vulvovaginal-candidiasis-market-A324411#:~:text=The%20global%20drugs%20for%20vulvovaginal,4.4%25%20from%202024%20to%202033.>

15 <https://finance.yahoo.com/news/global-vulvovaginal-candidiasis-treatment-market-224500866.html>

The market's growth is further driven by the rising prevalence of acute vulvovaginal candidiasis infections among the global population, with an increasing number of research initiatives aimed at understanding the prevalence of conditions like recurrent vulvovaginal candidiasis (RVVC).

According to an NCBI article, VVC is a common infection among women, affecting around 138 million women annually worldwide. Strong emerging pipelines with recent approvals of therapies in disease management, rising disease burdens, and the launch of new drugs, such as BREXAFEMME and VIVJOA, are among the primary factors driving the industry's growth. The global rise in VVC infection in women is such that it affects nearly 75% of women who report disease occurrence at least once in their lifetime.

According to an NCBI article, globally, complicated VVC affects around 10-20% of women, and 8% of women report recurrent VVC cases. Furthermore, an upsurge in the prevalence of the disease is observed due to increasing diabetic patients and rising antibiotic resistance cases among individuals. Around 15% of such cases are also estimated to require special therapeutic considerations. Thus, the rising prevalence of the disease is driving industry growth. The increasing demand for better therapeutic options is leading to innovations in R&D, new approvals, and launches of drugs, thereby creating a lucrative opportunity for industry growth.



Source: "Vulvovaginal Candidiasis Treatment Market: Global Industry Analysis and Forecast, 2024, MMR".

The rapid increase and unrestrained usage of antibiotics led to the high prevalence of yeast infection and an increasing prevalence of Vulvovaginal Candidiasis, which are likely major drivers of the disease's growth in the forecast period.

The high growth can also be attributed to the rising disease burden of the disease and increasing testing rate. Positive changes, such as healthcare benefits by the government, increased awareness among consumers, and willingness to avail medical treatments, are also expected to drive the growth of the vulvovaginal candidiasis treatment market.

#### By type

The recurrent vulvovaginal candidiasis segment held the highest market share of over 45%, leading the global vulvovaginal candidiasis treatment market in 2023.

The segment is expected to maintain its trends during the forecast period. Recurrent vulvovaginal candidiasis (RVVC) is a complicated form of vaginal yeast infection. It occurs in less than 5% of women but has a significant economic impact.

Around 40-50% of VVC cases experience recurrent episodes. RVVC can be classified as idiopathic (with no known underlying causes) or secondary, which can be linked to factors like frequent antibiotic use, diabetes, or other host-related factors.

The underlying mechanisms of RVVC are not well understood, and most women with RVVC do not have identifiable predisposing conditions. Non-albicans Candida species like *C. glabrata* are found in 10-20% of women with recurrent VVC.

Recurrent VVC can be associated with coexisting dermatological conditions such as lichen sclerosis and immunosuppression like HIV infection. The increasing prevalence of RVVC, the need for prolonged treatments, growing awareness, and the development of effective drugs are expected to drive the growth of this segment.

#### By Drug type

The rising regulatory approvals for treating vulvovaginal candidiasis are expected to offer lucrative growth potential for the vulvovaginal candidiasis treatment market players during the forecast period. Topical medications for the vulvovaginal candidiasis treatment have experienced a notable increase in regulatory approvals by various authorities such as the U.S. Food and Drug Administration (FDA), etc. according to the analysis, currently, the FDA has approved medications designed to address Mycovia, a pharmaceutical company specializing in antifungal treatments. These approved medications include oteseconazole, the first product from Mycovia to receive FDA approval.

Oteseconazole is categorized as an azole antifungal and is indicated for reducing the occurrence of Recurrent Vulvovaginal Candidiasis (RVVC). Additionally, ibrexafungerp tablets, marketed as Brexafemme, have also been approved by the FDA. Healthcare professionals commonly prescribe both oteseconazole and ibrexafungerp tablets (Brexafemme) for the treatment of vaginal yeast infections, including vulvovaginal candidiasis (VVC). These medications have gained significant popularity among medical practitioners for their effectiveness in addressing such infections.

The fluconazole segment dominated the global industry in 2023 and accounted for the maximum overall revenue share. Oral treatment with a single fluconazole dose effectively treats uncomplicated VVC. Treatment of complicated VVC is prolonged and most commonly consists of multiple doses of oral fluconazole. Thus, the need for fluconazole to treat VVC is increasing, driving the segment's growth.

However, with the entry of BREXAFEMME and Mycovia in the space, Fluconazole share is expected to decline over the coming years.

Nevertheless, these novel drugs come with higher pricing, which could slow down their market penetration. Clotrimazole, an antimycotic agent, was first registered under the brand name Canesten in Germany in 1973. Canesten is still among the leading brands for the treatment of vulvovaginal candidiasis.

Later, external cream, internal vaginal cream, and soft capsule (soft ovule) were available. The industry has the presence of different formulations under different trade names, such as Abzorb, Candid-V, Mycoderm-C, Surfaz, Kansel, Imidil, Orasep OT, and Cloben.

In many countries, mono preparations of clotrimazole are available over the counter in a dose range of 100 to 500mg. Furthermore, the drug is also available in combinations, such as clotrimazole with fluconazole, for effective disease management. All such factors support the industry's growth.

FDA approved nystatin in 1971, and it is sold under various brand names, such as Mycostatin, Bio-Statin, Pediaderm AF, Nystat, Nystop, and Nilstat. It is available for suspension in various forms, such as a tablet, cream, ointment, troches, and powder. Nystatin has proved effective in fluconazole-resistant Candida. The drug mimics the immunoregulatory role by increasing the levels of IL-17 and IFN-gamma to improve antifungal immunity in the vagina. All these factors are anticipated to drive industry growth.

*Source: "Vulvovaginal Candidiasis: A Review of the Evidence for the 2021 Centers for Disease Control and Prevention of Sexually Transmitted Infections Treatment Guidelines, 2022".*

Regimen	Dosing
Over-the-counter intravaginal agents:	
Clotrimazole 1% cream	5g intravaginally daily for 7–14 days
Clotrimazole 2% cream	5g intravaginally daily for 3 days
Miconazole 2% cream	5g intravaginally daily for 7 days
Miconazole 4% cream	5g intravaginally daily for 3 days
Miconazole 100mg vaginal suppository	One suppository daily for 7 days
Miconazole 200mg vaginal suppository	One suppository for 3 days
Miconazole 1200mg vaginal suppository	One suppository for 1 day
Tioconazole 6.5% ointment	5g intravaginally in a single application
Prescription intravaginal agents:	
Butoconazole 2% cream (single dose bioadhesive product)	5g intravaginally in a single application
Terconazole 0.4% cream	5g intravaginally daily for 7 days
Terconazole 0.8% cream	5g intravaginally daily for 3 days
Terconazole 80mg vaginal suppository	One suppository daily for 3 days
Oral agent:	
Fluconazole 150 gm	Single dose

The following table presents the common pricing per regimen for the typically purchased treatments:

Regimen	Price
<u>Over-the counter intravaginal agents</u>	
Clotrimazole 1% cream	~\$3-\$5
Clotrimazole 2% cream	~\$4-\$6
Miconazole 2% Cream	~\$6-\$8
Miconazole 4% Cream	~\$6-\$8
Miconazole 100mg vaginal suppository	~\$10-\$12
Miconazole 200mg vaginal suppository	~\$12-\$15
Miconazole 1200mg vaginal suppository	~\$35-\$40
Tioconazole 6.5% ointment	~\$10-\$15
<u>Prescription intravaginal agents</u>	
Butoconazole 2% cream	~\$69-\$80
Terconazole 0.4% cream	~\$20-\$30
Terconazole 80mg vaginal Suppository	~\$40-\$50
<u>Oral Agent</u>	
Fluconazole 150 gm	~\$25-\$30
Nystatin 100000 untis/ml	~\$40-\$50
Nystatin 500000 untis/ml	~\$130-\$150
Oteseconazole 5 mg	~\$300-\$350
Oteseconazole 10 mg	~\$500-\$550
Oteseconazole 50 mg	~\$1,500-\$1,800
Ibrexafungerp 25 mg	~\$1,800-\$2,00
Ibrexafungerp 50 mg	~\$3,000-\$3,200
Ibrexafungerp 100 mg	~\$4,500-\$4,800

The average price for over-the-counter intravaginal agents is between \$3 and \$40, depending on the product's purchase amount, while prescription intravaginal agents cost between \$20 and \$80.

Overall, the oral agents have significantly higher pricing. As mentioned above, treating RVCC usually requires the use of oral agents such as Oteseconazole and Ibrexafungerp.

#### By Treatment type

Vulvovaginal candidiasis usually responds rapidly to topical or oral antifungal therapy, but a chronic subtype has recently been described. However, some women develop recurrent vulvovaginal candidiasis, which is arbitrarily defined as four or more episodes every year. Suppressive therapy is used in these patients, which normally provides full resolution of symptoms for the duration of the treatment.

The treatment market includes oral therapy and antifungal pessaries and single (fluconazole) or two-dose (itraconazole). Many different topical azoles are sold, many generics, with good efficacy for single-episode vulvovaginal candidiasis.

The oral segment dominated the industry in 2022 and accounted for a maximum share of more than 43.2% of the total revenue. The oral segment is expected to grow at a CAGR of 5.50% during the forecast period and hold the

highest market share by 2029. It is anticipated to maintain its share throughout the forecast period owing to the common and convenient route of administration for azoles, good bioavailability, and use of anti-fungal drugs.

Oral fluconazole is the most common prescription drug recommended as treatment and maintenance therapy. It is also effective as short-duration therapy in recurrent VVC cases. Recently, the FDA has approved two oral dosage regimes of VIVJOA (oteseconazole) to reduce the incidences of recurrent VVC.

Additionally, the convenience and effectiveness of oral medications contribute to their popularity among patients and healthcare providers. The development and launch of more advanced and potent antifungal drugs further contribute to the segment's growth and increase the revenue share of the vulvovaginal candidiasis treatment market during the forecast period.

The topical segment is expected to grow at a steady CAGR during the study period. A strong presence of topical products such as over-the-counter and prescription formulations boosts the market's demand. OTCs include Clotrimazole cream, Miconazole cream, and Tioconazole ointment, whereas Butoconazole cream and Terconazole cream are prescription formulations.

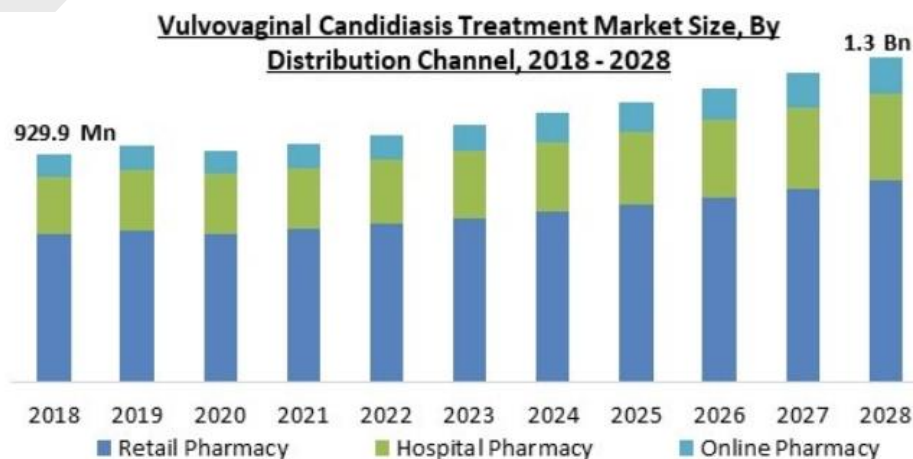
Furthermore, topical antifungal recommendations include econazole and nystatin, which have been on the market for over 30 years. According to IDSA guidelines, uncomplicated VVC should be treated with topical antifungal agents. Furthermore, oral azoles are ineffective in treating. Glabrata vulvovaginitis, thereby, is prescribed for topical intravaginal boric acid or topical flucytosine cream.

#### By Distribution channel

The industry has been categorized into retail, online, and hospital pharmacies. The retail pharmacy segment is expected to witness the fastest CAGR of more than 4.70% over the forecast period.

Disease treatment, control, and management require short—and long-term support of medications, which boosts the segment's growth. The market has prescription and OTC drugs. Pharmacists play an essential role by counseling patients and gaining their trust. Retail pharmacies are at ease with most medications, especially in the homecare setting. All these factors are expected to fuel the segment's growth.

The online pharmacy distribution channel segment is also expected to grow at a significant CAGR during the forecast period. The preference for online purchasing is high due to the convenience and other benefits, such as home delivery. Amid the pandemic, people experienced the comfort of delivery services and reduced travel time for prescription fill-in retail stores. The COVID-19 pandemic boosted the online segment due to government restrictions like nationwide lockdowns and stay-at-home orders to curb the spread of the virus.



Source: "Vulvovaginal Candidiasis Treatment Market Size, Share & Industry Trends Analysis Report, 2022, Research and Markets".

### By Region

The industry has been categorized into North America, Asia Pacific, Latin America, Europe, Middle East & Africa. North America dominated the global industry in 2023 and accounted for the maximum share of more than 40% of the overall revenue.

The region is expected to expand further at a steady growth rate, maintaining its dominant position throughout the forecast period. This dominance can be attributed to the high disease prevalence, the rise in patient awareness, increased healthcare expenditure, and the presence of major players in the region.

A recent Harvard study showed that approximately 6 million American women suffer from Vulvovaginal candidiasis. This region's established healthcare infrastructures, the high frequency of disease, and the presence of essential manufacturers are significant factors contributing to its market share. Advanced therapeutic options, new approvals, launches, and proactive government measures further contribute to regional market growth.

Rising clinical trials and research and development activities in North America are expected to support the vulvovaginal candidiasis treatment market's revenue growth. For example, in June 2021, the FDA granted authorization to BREXAFEMME, primarily for treating Vulvovaginal Candidiasis (VVC).

In November 2023, the FDA approved its secondary use for preventing recurrent VVC. Additionally, ongoing late-stage clinical trials are investigating Ibrexafungerp's effectiveness in treating severe invasive fungal infections in hospitalized patients.

The U.S. is expected to lead the regional market by 2030 due to increasing research and product development activities, increasing patient population, governmental initiatives to raise awareness of the conditions, etc. According to the MMR analysis, around 149,934 women in the United States were diagnosed with Vulvovaginal Candidiasis (VVC) in April 2023, with 3.4% of them experiencing recurrent VVC (RVVC). The South census region had the highest VVC rate, standing at 14.3 cases per 1,000 female patients. This high prevalence of vaginal



candidiasis is driving the demand for new therapeutics and contributing to the vulvovaginal candidiasis treatment market growth in the country.

On the other hand, Asia Pacific is estimated to witness the fastest growth rate over the forecast years. The high growth rate can be attributed to the rising disease burden of VVC and increasing testing rates. Positive changes, such as the government's healthcare benefits, increased awareness among consumers, and willingness to avail of medical treatments, are also expected to drive growth in the region.

India has a large population of women, and the prevalence of VVC is relatively high in the country. Factors such as poor hygiene practices, tropical climate, and the widespread use of antibiotics contribute to the increased incidence of VVC among women in India. Additionally, rising awareness about women's health issues and increasing healthcare expenditure are driving demand for VVC treatment options, thus boosting the market for vulvovaginal candidiasis treatment in the country.

Europe is one of the top regions driving vulvovaginal candidiasis treatment demand, and prospects are being boosted by the presence of a well-developed healthcare infrastructure and the availability of skilled medical staff.

Europe's market is expected to grow at a robust rate; the region invests in biopharmaceutical research and development to develop cures for uncommon diseases, which bodes well for vulvovaginal candidiasis treatment system providers in the region.

The Europe Vulvovaginal Candidiasis Treatment Market will witness market growth of 4.2% CAGR during the forecast period (2022-2028)<sup>16</sup>.

According to the National Institute of Health, in Germany, a significant portion of healthy women, around 70-75%, experience vulvovaginal candidiasis at least once in their lifetime. This corresponds to approximately 3619 cases per 100,000 women aged 15-54. Notably, many of these women face recurrent episodes of VVC, with more than four occurrences per year, which is defined as recurrent VVC (RVVC).<sup>17</sup>

These statistics highlight the substantial burden of VVC among women in Germany, underscoring the importance of effective management and treatment strategies to address this prevalent condition. This increased prevalence contributes to the growth of the market.

### Patent Analysis

The patent analysis for drugs treating vulvovaginal candidiasis, as per data from the World Intellectual Property Organization (WIPO) between 2016 and 2023, reveals significant regional contribution to innovation in this field. The U.S. leads the patent landscape with 26.7% of global filings, reflecting its strong pharmaceutical and healthcare research sectors. Australia and China follow closely, each contributing 20% of patents, showcasing

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<sup>16</sup> <https://www.kbvresearch.com/europe-vulvovaginal-candidiasis-treatment-market/>

<sup>17</sup> <https://www.gminsights.com/industry-analysis/vulvovaginal-candidiasis-treatment-market>

their growing investments in women's health and antifungal treatments; India and the Russian Federation each account for 13.3%, indicating emerging research efforts in these regions.

Argentina represents 6.7% of the global patent filings, demonstrating a more minor but meaningful contribution to antifungal drug innovation. This data highlights the global nature of advancements in treating vulvovaginal candidiasis, with both established and emerging economies playing key roles in developing new therapies.

### Key Companies

Major players are undertaking various strategic initiatives, such as geographical expansion, merger, and acquisition, to gain a higher market share. Moreover, companies are focusing on gaining approvals for novel products that have the potential to address unmet needs. For instance, Mycovia Pharmaceuticals' VIVJOA, already approved in some European, Asian, and Latin American countries, received FDA approval for recurrent VVC treatment in the U.S. in August 2022.

In June 2023, Scynexis Inc. announced a study of Phase 3 clinical trials for Fluconazole Tablet and IBREXAFUNGERP. This research is a Phase 3 clinical trial conducted at multiple centers. It is a randomized, double-blind study comparing the effectiveness and safety of oral ibrexafungerp (previously known as "SCY-078") to a placebo. The study focuses on female participants aged 12 and above who suffer from recurrent vulvovaginal candidiasis (RVVC).

In September 2023, Ege University announced a study of Phase 3 clinical trials for EVEGYN A and Gynomax® XL Vaginal Ovule. In this multicenter, randomized study, the effectiveness and safety of two new formulations were assessed in comparison to Gynomax® XL ovule for treating trichomonal vaginitis, bacterial vaginosis, candidal vulvovaginitis, and mixed vaginal infections.

In February 2024, Sano Chemicals initiated its phase I, first-in-human clinical trial of Occidiofungin, a novel therapy for recurring vaginal yeast infections or vulvovaginal candidiasis. Occidiofungin is a fungicide that is being developed as a cure for infection rather than suppressive medication.

In January 2024, Hyloris Pharmaceuticals SA announced positive outcomes for the phase 2 trial of Miconazole Domiphen-Bromide (MCZ-DB) in individuals with acute vulvovaginal candidiasis. Both treatment arms with Miconazole (2%) and Domiphen Bromide (0.14% or 0.29%) showed excellent safety and tolerability.

## North America Vulvovaginal Candidiasis Market

The North America Vulvovaginal Candidiasis Treatment Market should witness market growth of 3.9% CAGR during the forecast period (2022-2028)<sup>18</sup>.

The vaginal cultures should be performed for the women with negative results but have symptoms of VVC and proper treatment is required for those with positive results. Empiric treatment is considered appropriate if candida cultures cannot be performed. Most of the PCR tests for yeasts are not approved by the FDA, so the providers should be familiar with the performance characteristics of the test they are using.

A recurring VVC condition, defined as three or more episodes of having VVC symptoms in a year, affects more than 5% of women and causes a substantial economic concern. The recurrence of vulvovaginal candidiasis could be idiopathic or secondary and related to continuing diabetes, antibiotic use, or other such factors.

In most cases, recurrent VVC caused by *C. albicans* can be treated by short-duration oral and topical azole therapies. However, to maintain clinical and mycologic control, gynecologists suggest a longer duration of initial therapy. An example of longer-duration therapy is either 7-14 days of topical therapy or an oral dose of 100 mg, 150 mg, and 200 mg of fluconazole every third day three times, which means days 1, 4, and 7.

The risk of women with HIV infection risk of vulvovaginal candidiasis is high. Women with HIV are more prevalent to have white adherent vaginal discharge, mucosal itching & burning. Furthermore, women with advanced immunosuppression could have VVC severe and recurrent episodes of VVC. As a result of the high prevalence of HIV in the region, the market for vulvovaginal candidiasis treatment will expand during the forecast period.

**The US market** dominated the North America Vulvovaginal Candidiasis Treatment Market by Country in 2021; thereby, achieving a market value of \$345.8 million by 2028. **The Canada market** is experiencing a CAGR of 6.3% during (2022-2028). Additionally, The Mexico market would exhibit a CAGR of 5.4% during (2022-2028).

An online survey<sup>19</sup> sent to 4,548 U.S. adults; data were weighted to be representative of the population. Among the subset of 1,869 women respondents, 98 (5.2%) had VVC in the past year; of those, 5 (4.7%) had RVVC. In total, 991 (53%) women reported healthcare provider-diagnosed VVC in their lifetime.

Overall, 72% of women with VVC in the past year reported prescription antifungal treatment use, 40% reported OTC antifungal treatment use, and 16% reported both. In multivariate analyses, the odds of having VVC in the past year were highest for women with less than a high school education, with a child under 18 years old, with diabetes, who were part of a couple, and with more visits to a healthcare provider for any reason. Similar factors were associated with the increasing number of VVC episodes in the past year and with the lifetime prevalence of VVC.

18 [https://www.researchandmarkets.com/reports/5709514/north-america-vulvovaginal-candidiasis-treatment?srsltid=AfmBOopxmSSOtou-YMjMnDlqF4jySUDE3TaADfpCNld\\_VQDVjqm2X8E](https://www.researchandmarkets.com/reports/5709514/north-america-vulvovaginal-candidiasis-treatment?srsltid=AfmBOopxmSSOtou-YMjMnDlqF4jySUDE3TaADfpCNld_VQDVjqm2X8E)

19 <https://pmc.ncbi.nlm.nih.gov/articles/PMC9092842/>

In this study, the annual incidence of self-reported healthcare provider-diagnosed VVC (5.2%) and RVVC among those with VVC (4.7%) suggests that ~6.8 million women experience VVC and ~325,000 experience RVVC in the United States each year, based on an estimated 2019 population of 130,851,717 women aged 18 and older. Although the number of survey respondents reporting RVVC in the past year was small, these projections show that the number of VVC and RVVC cases may be substantial, in accordance with a previous study that showed a significant healthcare burden of nearly 1.4 million outpatient visits and \$374 million in direct medical costs related to VVC each year.

## Europe Vulvovaginal Candidiasis Market

The Europe Vulvovaginal Candidiasis Treatment Market will witness market growth of 4.2% CAGR during the forecast period (2022-2028)<sup>20</sup>.

In 2019, about 105,200 people had HIV infection in the United Kingdom; out of these, 6600 cases were predicted undiagnosed. Also, obesity continued to be among the region's significant concerns of public health. Being overweight and obese raises the risk of developing various diseases. Obese people are more at risk of insulin resistance, high blood sugar levels, and the development of diabetes. The increased blood sugar level could result in overgrowth of Candida, especially in the genitals or bladder. Furthermore, the consumption of antibiotics to treat the urinary tract could also lead to candida-related infection. As a result, the rising prevalence of obesity would further raise the occurrence of vulvovaginal candidiasis in the region.

The Germany market dominated the Europe Vulvovaginal Candidiasis Treatment Market by Country in 2021; thereby, achieving a market value of \$88.5 million by 2028. The UK market is exhibiting a CAGR of 3.3% during (2022 - 2028). Additionally, The France market would experience a CAGR of 5% during (2022 - 2028).

Based on the Distribution Channel, the market is segmented into Retail Pharmacy, Hospital Pharmacy, and Online Pharmacy. Based on the Route of Administration, the market is segmented into Oral, Intravenous, and Topical. Based on Drug Class, the market is segmented into Fluconazole, Clotrimazole, Terconazole, Terbinafine, Nystatin, Ketoconazole, and Others. Based on countries, the market is segmented into Germany, the UK, France, Russia, Spain, Italy, and the Rest of Europe.

## Conclusions

**The global** vulvovaginal candidiasis treatment market size was valued at USD 1,423 million in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 5.25% from 2024 to 2030, reaching USD 2,037.09 million and a compound annual growth rate (CAGR) of 4.4% from 2024 to 2033.

The rising prevalence of Vulvovaginal Candidiasis among women, increasing risk of recurrent Vulvovaginal Candidiasis, driving the demand for new therapeutics for treatment, augmenting the Vulvovaginal Candidiasis treatment market's growth. In addition, the growing awareness of candidiasis infection among the target population and rising product innovation across the world to cure candidiasis are expected to be the further factors driving the demand for new therapeutics.

Up to 75% of women will have at least one vaginal yeast infection in their life<sup>21</sup>, Moreover, recurrent VVC (Vulvovaginal Candidiasis) affects nearly 8% of women globally (for women above the ages of 15-60).

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<sup>20</sup> <https://www.kbvresearch.com/europe-vulvovaginal-candidiasis-treatment-market/>

<sup>21</sup> <https://my.clevelandclinic.org/health/diseases/5019-vaginal-yeast-infection>

Recurrent VVC is defined as having more than 4 episodes of VVC. According to the data above, 100% of women with Recurrent VVC will purchase a combination of over-the-counter and prescription antifungal treatments, usually with the common use of oral agents. Compared to women with non-recurrent VVC, 55.2% will purchase prescription antifungal treatment, 37% over-the-counter antifungal, 5.6% will purchase a combination of both treatments, and the rest will not purchase any treatment.

North America dominated the global industry in 2023 and accounted for the maximum share of more than 40% of the overall revenue. **The US market** dominated the North America Vulvovaginal Candidiasis Treatment Market by Country in 2023; thereby, achieving a market value of \$345 million by 2028. **The Canada market** is experiencing a CAGR of 6.3% during (2022-2028).

**The European** vulvovaginal Candidiasis Treatment Market will grow at a 4.2% CAGR during the forecast period (2022-2028). Europe is one of the top regions driving vulvovaginal candidiasis treatment demand, and prospects are being boosted by the presence of a well-developed healthcare infrastructure and the availability of skilled medical staff. Europe's market is expected to grow at a robust rate; the region invests in biopharmaceutical research and development to develop cures for uncommon diseases, which bodes well for vulvovaginal candidiasis treatment system providers in the region.

In conclusion, the vulvovaginal candidiasis treatment market is a fast-growing market, effected by the increasing prevalence, growing awareness and high demands. The market has an estimation of reaching over USD 2 billion by 2030, with a compound annual growth rate of 5.25% globally and 3.9% in North America and 4.2% in Europe.