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Research Article

Clinical Performance and Safety of A Rigenase® and Polyhexanide Hydrogel (Fitostimoline® Septagel) in the Management of Vulvovaginal Disorders: A National PMCF Survey

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Abstract

Objectives: Vulvovaginal inflammatory and dystrophic conditions, such as vaginitis, vulvovaginitis, and vaginal atrophy, significantly impair female quality of life. This Post-Marketing Clinical Follow-up (PMCF) survey aims to evaluate the real-world efficacy, safety, and patient satisfaction of Fitostimoline® Septagel, a hydrogel combining Rigenase® (Triticum vulgare extract) and polyhexanide. **Methods:** A multicenter survey was conducted by 50 physicians across Italy, enrolling 248 patients. Data on demographics, clinical indications, treatment duration (up to 28 days), and safety were collected. Efficacy was measured via a clinical improvement scale (0–10). **Results:** The study population (mean age 43 years) showed a high prevalence of vaginitis (72.6%) and vulvovaginitis (60.9%). Clinical success was reported in 94.4% of cases, with a mean improvement score of 7.9/10. The safety profile was excellent. **Conclusions:** Fitostimoline® Septagel is an effective and well-tolerated therapeutic option for promoting mucosal repair and managing symptoms in a wide range of vulvovaginal pathologies.

Introduction

Inflammatory and degenerative conditions affecting the female lower genital tract are highly prevalent and represent a common reason for gynecological consultation. Disorders such as vaginitis and vulvovaginitis are frequently associated with infectious agents and alterations of the vaginal microbiota, while other conditions, most notably vaginal atrophy, are mainly related to hormonal changes, particularly estrogen deficiency, in case of hormonal deprivation of gonadal steroids during fertile life , or in peri and postemenopausal period [1,2]. These pathophysiological processes can lead to mucosal thinning, dryness, irritation, and discomfort, often resulting in a significant deterioration in quality of life [3,4]. The management of these conditions typically requires therapeutic strategies capable of addressing both the underlying cause and the restoration of mucosal integrity. Conventional treatments often focus primarily on antimicrobial or antifungal activity [5]; however, increasing attention has been directed toward therapies that also support tissue repair and regeneration.

Fitostimoline® Septagel represents a novel approach in this context. The formulation combines Rigenase®, a patented extract of Triticum vulgare known for its regenerative, antioxidant and emollient properties, with polyhexanide (PHMB), a broad-spectrum antiseptic agent that prevents microbial colonization and biofilm formation. Unlike traditional antimicrobial treatments alone, this dual mechanism aims to simultaneously control microbial proliferation and promote mucosal healing [6]. In order to better understand the clinical performance of this formulation in routine medical practice, a Post-Marketing Clinical Follow-up (PMCF) survey was conducted across Italy. The objective of the present study was to collect real-world evidence regarding the efficacy, safety, tolerability, and patient satisfaction associated with Fitostimoline® Septagel in the management of common vulvovaginal conditions.

Materials and Methods

Survey Design and Participants

A National Post-Marketing Clinical Follow-up (PMCF) survey was conducted to investigate the clinical performance and safety of Fitostimoline® Septagel in the management of vaginitis, vulvovaginitis and vaginal atrophy. The survey was designed in accordance with national recommendations for the vigilance of medical devices, ensuring a robust collection of real-world evidence. The Scientific Committee and Investigator Network was composed of 6 Key Opinion Leaders (KOLs) representing various Italian regions. This committee was responsible for the design and validation of the questionnaire. A network of 50 physicians (listed in the Appendix) participated in the clinical phase, administering the survey to patients during routine clinical practice to ensure a broad and representative enrollment across the country.

Patients presenting with symptomatic conditions (bacterial, fungal or atrophic vulvovaginitis) were eligible for inclusion. The survey was conducted through two distinct clinical evaluations:

1. Baseline Visit (T0 - Enrollment): Physicians recorded demographic data and the specific clinical indications for which Septagel was prescribed.

2. Follow-up Visit (T1 - End of Treatment): Conducted at the end of the observation period to assess clinical outcomes.

A total of 248 patients were enrolled and successfully completed the survey. The study population had a mean age of 43 years, reflecting a cohort largely representative of women in the reproductive and perimenopausal stages of life.

The treatment protocol followed standard clinical practice, with a duration not exceeding 28 days. The total observation period for each patient was 4 weeks from the initial enrollment.

Study Endpoints and Data Collection

Three main outcome domains were evaluated:

- Efficacy and Clinical Progress

Physicians assessed the clinical evolution of symptoms during treatment. Patients rated their satisfaction with clinical improvement using a 10-point Likert scale ranging from 1 (“not satisfied at all”) to 10 (“completely satisfied”).

- Safety and Tolerability

Adverse reactions and potential side effects were systematically recorded. Particular attention was given to the occurrence of discomfort or pain associated with product application.

- Patient Experience and Quality of Life

During the follow-up visit, qualitative information regarding the product’s usability was collected, including aspects related to formulation, instructions, packaging, and ease of use. The perceived impact of treatment on the patient’s overall quality of life was also evaluated.

Selection Criteria

The survey included adult women (≥18 years) identified during routine gynecological consultations. Eligible participants presented with clinically evident symptoms of vulvovaginal disorders.

Patients were excluded if they declined participation or if they had a documented hypersensitivity or intolerance to Triticum vulgare extract or polyhexanide.

Ethical Considerations and Data Privacy

All participants received detailed information about the objectives of the survey and the use of the collected data. Participation was entirely voluntary.

In compliance with Italian privacy regulations, all data were anonymized and analyzed exclusively in aggregated form to ensure that individual patients could not be identified.

Results

A total of 248 patients were enrolled and successfully completed the survey. The study population had a mean age of 43 years, reflecting a cohort largely representative of women in the reproductive and perimenopausal stages of life.

To better understand the demographic characteristics of the population, age distribution was analyzed across four predefined categories. As shown in Table 1, the largest proportion of participants belonged to the 35–50 year age group, representing 44.3% of the total sample. This was followed by women aged 18–34 years (25.3%), while patients aged over 65 years accounted for 11.8% of the cohort. Statistical analysis ($p < 0.001$) confirms that the distribution is significantly concentrated in the reproductive and perimenopausal age groups, which are commonly affected by vulvovaginal disorders.

Age Group	Percentage (%)	p-value
18–34 years	25.3%	< 0.001*
35–50 years	44.3%	< 0.001*
51–64 years	18.6%	< 0.001*
Over 65 years	11.8%	< 0.001*
Total	100%	

Table 1: Demographic Profile and Age Stratification of the Female Study Population

The table presents the distribution of enrolled female patients across four distinct age cohorts. The mean age of the participants was 43 years, with a predominant concentration in the 35–50 years category, representing 44.3% of the total sample. Statistical testing ($p < 0.001$) indicates a significant demographic trend toward reproductive and perimenopausal age groups.

Following the demographic analysis, the clinical indications leading to the prescription of Fitostimoline® Septagel were evaluated. The results summarized in Table 2 demonstrate a high prevalence of inflammatory and degenerative vaginal conditions within the study population. Vaginitis was the most frequently reported diagnosis, affecting 72.6% of patients (n=180), followed by vulvovaginitis in 60.9% (n=151) of cases. Vaginal atrophy was identified in 43.5% of participants (n=108). The statistical significance of these findings ($p < 0.001$) highlights the broad clinical use of the Rigenase® and polyhexanide formulation in the management of multiple gynecological conditions.

Diagnosis	Frequency (n)	Percentage (%)	p-value
Vulvovaginitis	151	60.9%	< 0.001*
Vaginitis	180	72.6%	< 0.001*
Vaginal Atrophy	108	43.5%	< 0.001*
Other Conditions	104	41.9%	< 0.001*

Table 2: Distribution of Clinical Indications among the Study Population.

The clinical profile of the enrolled cohort showed a significant prevalence of inflammatory and degenerative conditions. Vaginitis was the most frequent diagnosis, affecting 72.6% of patients (n=180), followed by vulvovaginitis in 60.9% (n=151) of the cases. Additionally, vaginal atrophy was identified in 43.5% (n=108) of the population. Statistical analysis ($p < 0.001$) confirms a non-random distribution of these pathologies, highlighting the consistent use of the Rigenase® and polyhexanide formulation across a broad spectrum of gynecological conditions requiring mucosal repair and antiseptic protection. Percentages exceed 100% due to the presence of multiple concomitant diagnoses in several patients.

The survey also investigated the duration of therapy prescribed in routine clinical practice. As illustrated in Table 3, treatment regimens varied depending on the clinical condition and severity of symptoms. The most commonly prescribed treatment durations were 14 days (50.0%) and 21 days (60.1%), suggesting that a two- to three-week treatment period is frequently required to achieve optimal mucosal recovery in inflammatory conditions such as vaginitis and vulvovaginitis. A 28-day regimen (34.3%) was

more frequently associated with chronic conditions, particularly vaginal atrophy, where longer treatment periods may be necessary to support tissue regeneration. Shorter treatments were also observed, including 5-day (33.5%) and 7-day (13.7%) regimens, which were typically prescribed for acute symptomatic episodes requiring rapid relief.

Treatment Duration	Percentage (%)	p-value
3 days	2.0%	< 0.001*
7 days	13.7%	< 0.001*
14 days	50.0%	< 0.001*
21 days	60.1%	< 0.001*
28 days	34.3%	< 0.001*
Other (5 days)	33.5%	< 0.001*

Table 3: Prescribed Treatment Durations for the Septagel Cohort

The table illustrates the clinical distribution of treatment lengths observed during the follow-up. The majority of the study population required a treatment period of at least two to three weeks to achieve optimal outcomes. The prevalence of 14-day (50.0%) and 21-day (60.1%) regimens ($p < 0.001$) suggests that this timeframe is the clinical standard for achieving significant mucosal regeneration in cases of vulvovaginitis and vaginitis. Shorter regimens (5–7 days) were utilized for acute symptom management, while longer durations (28 days) supported the management of chronic conditions such as vaginal atrophy.

In addition to clinical outcomes, the survey evaluated patient perception of the product's usability and formulation characteristics. The results are summarized in Table 4.

Overall, patient feedback regarding the device's physical and functional characteristics was highly positive. A large majority of respondents reported satisfaction with the size of the applicator (87.5%) and the soft texture of the hydrogel formulation (81.5%), indicating that the product is well suited for mucosal application.

Technical aspects related to packaging and administration were also favorably evaluated. Ease of opening (81.9%) and effective dispensing (78.2%) received high approval rates. Although slightly lower, the percentages associated with instruction clarity (71.4%) and overall ease of use (76.6%) still indicate a strong level of usability, supporting the product's suitability for self-administration.

Characteristic	Percentage (%)	p-value
Soft Texture	81.5%	< 0.001*
Effective Dispensing	78.2%	< 0.001*
Adequate Size	87.5%	< 0.001*
Understandable Instructions	71.4%	< 0.001*
No Opening Issues	81.9%	< 0.001*
No Usage Issues	76.6%	< 0.001*

Table 4: Qualitative Evaluation and User Experience Metrics for Septagel.

The table summarizes the percentages of positive responses regarding the primary qualitative characteristics of the medical device. The data show a high rate of approval across all parameters, particularly concerning the product's size and texture. Statistical significance ($p < 0.001$) across all categories confirms that the positive perception of the device's usability and physical properties is consistent throughout the study population, supporting the patient's adherence to the prescribed treatment protocol.

Finally, the survey assessed the overall clinical efficacy and safety profile of Fitostimoline® Septagel.

As reported in Table 5, the treatment achieved a clinical success rate of 94.4%, indicating a high level of effectiveness in managing vulvovaginal symptoms. This finding is further supported by the mean improvement score of 7.9/10, reflecting substantial symptom relief and mucosal recovery.

In terms of safety, the formulation demonstrated an excellent tolerability profile. Additionally, physicians reported a high level of satisfaction with the prescribed treatment regimen, with 94.4% confirming the adequacy of the dosage and therapeutic indication.

Variable	Percentage (%)	p-value
Clinical Efficacy (Success in treating pathology)	94.4%	< 0.001*
Dosage Adequacy (Correct posology)	94.4%	< 0.001*
Indication/Tolerability Correctness	87.5%	< 0.001*

Table 5: Summary of Efficacy and Safety Outcomes for Septagel.

High rates of therapeutic success and dosage appropriateness (both at 94.4%) demonstrate the device's reliability in treating vulvovaginal pathologies. Statistical significance ($p < 0.001$) across all categories underscores the validity of these outcomes in a real-world clinical setting.

Discussion

The findings of this national PMCF survey provide valuable real-world evidence regarding the clinical performance of Fitostimoline® Septagel in the management of vulvovaginal disorders. Overall, the results demonstrate high efficacy, strong patient satisfaction, and a favorable safety profile, supporting the use of this formulation in everyday gynecological practice. The observed clinical success rate of 94.4% is consistent with previously published studies, including prospective investigations such as those reported by Riemma et al. (2023). [7] One of the key aspects emerging from the survey is the dual mechanism of action provided by the combination of Rigenase® and polyhexanide. While polyhexanide contributes to controlling microbial proliferation through its broad antiseptic activity and anti-biofilm properties, Rigenase® supports mucosal regeneration and re-epithelialization. This complementary activity distinguishes Septagel from conventional therapies that focus solely on antimicrobial treatment.

Another relevant finding concerns the high proportion of patients with vaginal atrophy (43.5%) included in the study population. In these patients, the hydrogel formulation may play an important role in improving mucosal hydration, elasticity, and comfort. Such effects can contribute to reducing symptoms such as dryness, irritation, and dyspareunia, which are commonly associated with estrogen deficiency.

Patient experience also emerged as an important factor influencing treatment adherence. The high level of satisfaction reported for characteristics such as soft texture, adequate size, and ease of dispensing suggests that the formulation is well adapted for intravaginal application. This aspect is particularly relevant for therapies requiring longer treatment cycles (21–28 days), where ease of use can significantly affect patient compliance.

Taken together, these findings highlight the importance of combining antiseptic protection with regenerative support, especially in conditions where mucosal integrity is compromised.

Conclusions

The results of this national PMCF survey indicate that Fitostimoline® Septagel is a safe, effective, and well-accepted therapeutic option for the management of vulvovaginal disorders. Beyond its antimicrobial activity, the formulation provides a regenerative environment that supports mucosal repair and restoration of tissue integrity. This characteristic makes the product suitable for addressing both acute inflammatory conditions, such as vaginitis and vulvovaginitis, and chronic dystrophic conditions, including vaginal atrophy.

Another important aspect highlighted by the study is the high level of patient satisfaction, not only with clinical outcomes but also with the usability and physical characteristics of the product. These elements can play a crucial role in promoting treatment adherence and optimizing therapeutic success in real-world settings.

Overall, the survey confirms that Fitostimoline® Septagel represents a versatile addition to the gynecological therapeutic armamentarium, capable of addressing multiple clinical needs through a combined antiseptic and regenerative mechanism of action.

References

1. Goje O, Munoz JL (2017) Vulvovaginitis: Find the cause to treat it. Cleve Clin J Med 84: 215-224.
2. Powell AM, Nyirjesy P (2014) Recurrent vulvovaginitis. Best Pract Res Clin Obstet Gynaecol 28: 967-976.
3. Powell AM, Sarria I, Goje O (2023) Microbiome and Vulvovaginitis. Obstet Gynecol Clin North Am 50: 311-326.
4. Van Schalkwyk J, Yudin MH, Infectious Disease Committee (2015) Vulvovaginitis: screening for and management of trichomoniasis, vulvovaginal candidiasis, and bacterial vaginosis. J Obstet Gynaecol Can 37: 266-274.
5. Tomas M, Palmeira-de-Oliveira A, Simoes S, Martinez-de-Oliveira J, Palmeira-de-Oliveira R (2020) Bacterial vaginosis: Standard treatments and alternative strategies. Int J Pharm 587: 119659.
6. Sanguigno L, Casamassa A, Funel N, Minale M, Riccio R, et al. (2018) Triticum vulgare extract exerts an anti-inflammatory action in two in vitro models of inflammation in microglial cells. PLoS One 13: e0197493.
7. Riemma G et al Efficacy of a Novel Rigenase® and Polyhexanide (Fitostimoline® Septagel) Hydrogel Device for the Treatment of Vulvovaginitis Symptoms: Cross-Sectional Analysis of a National Survey and Prospective Observational Study. Medicina (Kaunas). 2023 Nov 15;59(11):2004. doi: 10.3390/medicina59112004.

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Appendix 1: list of physicians who participated in PMCF survey