Journal of Surgery
Miracapillo A, et al. J Surg 11: 11617
www.doi.org/10.29011/2575-9760.11617
www.gavinpublishers.com
Research Article

Rigenase® and PHMB-based Formulations for the Management of Diverse Cutaneous Lesions: Results from a National Post-Marketing Clinical Follow-up (PMCF) Survey

Antonio Miracapillo[1*], Claudio Brescia[2], Giovanna Muto[3], Federica Filippi[4]

[1]Ospedale Generale Regionale "F.Miulli", Acquaviva delle Fonti (Bari), Italy

[2]Section of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy

[3]Azienda ULSS N. 4 Veneto Orientale, Italy

[4]AOU di Bologna Policlinico S.Orsola, Malpighi, Italy

***Corresponding Author:** Antonio Miracapillo, Ospedale Generale Regionale "F.Miulli", Acquaviva delle Fonti (Bari), Italy

Citation: Miracapillo A, Brescia C, Muto G, Filippi F (2026) Rigenase® and PHMB-based Formulations for the Management of Diverse Cutaneous Lesions: Results from a National Post-Marketing Clinical Follow-up (PMCF) Survey. J Surg 11: 11617 DOI: 10.29011/2575-9760.011617

Received Date: 20 April 2026; **Accepted Date:** 20 April 2026; **Published Date:** 22 April 2026

Abstract

Background: Chronic and acute skin lesions represent a major healthcare burden, particularly in aging populations. Efficient tissue regeneration combined with infection control is critical for successful healing.

Objective: To evaluate the clinical performance, safety, and user experience of a range of medical devices (Fitostimoline® Plus Cream, Fitostimoline® Plus Gauzes, Fitostimoline® Plus Gauzes Advance, and Fitostimoline® Plus Spray) containing Rigenase® and polyhexanide PHMB in a real-world setting.

Methods: A national Post-Marketing Clinical Follow-up (PMCF) survey was conducted on 538 patients. Data were collected via physician-administered questionnaires focusing on demographic stratification, wound types, treatment regimens, qualitative characteristics, and safety outcomes.

Results: The geriatric population (65+) was the primary user of gauze formulations (up to 69.4% for Fitostimoline® Plus Gauzes Advance), primarily for treating ulcers. Fitostimoline® Plus Cream and Fitostimoline® Plus Spray formulations showed higher versatility for acute wounds and abrasions. High levels of patient satisfaction were reported for texture (83.3%) and size (87.0%). Safety was robust and quality of life improved significantly for over 71% of patients across all groups.

Conclusions: The combination of Rigenase® and PHMB across multiple formulations provides an effective and safe therapeutic approach for various skin lesions, facilitating high patient adherence and improved quality of life.

Introduction

The integrity of the skin is the first line of defence against physical, chemical and microbial insults; when that barrier is breached, a tightly regulated sequence of inflammatory, proliferative and remodeling events must progress to achieve durable tissue repair [1,2]. In clinical practice-especially among older adults and patients with comorbidities such as diabetes, peripheral vascular disease or reduced mobility-this reparative cascade is frequently disrupted, leading to stalled healing, persistent inflammation, microbial colonization and the development of chronic lesions such as pressure injuries, venous and arterial ulcers, and non-healing surgical wounds. These clinical realities demand therapeutic approaches that go beyond simple coverage: ideal interventions should actively modulate the wound microenvironment to accelerate re-epithelialization, limit excessive inflammation and simultaneously control bioburden [3]. The Fitostimoline® Plus product family was developed with this dual requirement in mind. Its formulations combine a bioactive botanical fraction-Rigenase®, a standardized extract of Triticum vulgare that contains low-molecular-weight oligosaccharides and has been associated with antioxidant and regenerative effects-with PHMB (PHMB), a cationic antiseptic widely used in wound care for its broad antimicrobial spectrum and favourable tissue tolerability [4-6]. Together, these two components aim to create a wound milieu that supports progression from the inflammatory to the proliferative phase while maintaining low microbial load, thereby facilitating organized granulation tissue formation and re-epithelialization.

Fitostimoline® Plus products are available in multiple delivery systems-water-dispersible Fitostimoline® Plus Cream (ideal for direct application on superficial wounds and excoriated skin), single-use impregnated Fitostimoline® Plus Gauzes (for occlusive, protective contact dressings), Advanced impregnated Fitostimoline® Plus Gauzes (for more complex, exuding or chronic wounds) and Fitostimoline® Plus Spray (for non-contact application over large or difficult-to-dress areas). This formulation diversity reflects an explicit design principle: match the mechanical and microenvironmental needs of different lesion types (e.g., moisture balance, barrier protection, ease of application) without changing the core regenerative-plus-antiseptic chemistry. The approved indications described by the manufacturer and summarized in independent product monographs include ulcers, sores, traumatic wounds, first- and second-degree burns, scalds and abrasions. From an evidence perspective, randomized and observational studies have reported favorable outcomes with Rigenase®–PHMB combinations in acute and some chronic wound contexts, showing improved epithelialization and good tolerability compared with several standard comparators. At the same time, the antiseptic properties of PHMB and its role in reducing wound bioburden and slough are supported by clinical literature and reviews of PHMB-containing products. Nevertheless, controlled trials are often limited in size, scope or patient mix, and they do not always capture important real-world dimensions such as patient usability, adherence in home care, or product performance across diverse lesion types and care settings.

For these reasons, PMCF surveys are a necessary complement to pre-market evidence: they evaluate how a medical device performs in heterogeneous real-world populations, identify patterns of formulation selection across clinical contexts, and assess user-centred outcomes (usability, tolerability, patient-reported quality of life) that influence long-term adherence and effectiveness. The national PMCF survey reported here was therefore undertaken to (i) characterize the demographics and lesion profiles of patients treated with the Fitostimoline® Plus line, (ii) document real-world usage patterns for each formulation (frequency and duration), (iii) quantify safety and tolerability in routine practice, and (iv) capture patient-reported outcomes and practical usability metrics that support treatment persistence in outpatient and home settings. By linking mechanistic rationale (regeneration + antisepsis) with pragmatic performance data across the Fitostimoline® Plus Cream, Gauzes, Gauzes Advance and Spray formats, the survey sought to provide clinicians and health systems with a fuller understanding of where these products may be most beneficial and how they perform outside controlled trial conditions.

Materials and Methods

A national PMCF survey was conducted to evaluate the clinical performance, safety, and user experience of Fitostimoline® Plus formulations in the management of acute and chronic cutaneous lesions. The survey was designed in accordance with current national recommendations for medical device vigilance and post-market surveillance, with the aim of generating robust real-world evidence reflecting routine clinical practice. The study protocol and data collection tools were developed and validated by a Scientific Committee composed of Key Opinion Leaders (KOLs) in dermatology, wound care, and general medicine, representing different geographical areas. A nationwide network of participating physicians contributed to patient recruitment and data collection during standard outpatient visits, ensuring a heterogeneous and representative study population. A total of 538 patients presenting cutaneous lesions of varying etiology were included. Patients were enrolled consecutively during routine clinical practice, minimizing selection bias and reflecting real-life therapeutic decision-making.

The survey followed a cross-sectional observational design structured around two main timepoints:

1. Baseline Visit (T0–Enrollment): At inclusion, physicians recorded demographic characteristics (age and gender), clinical diagnosis, type of lesion (e.g., ulcers, pressure sores, burns,

abrasions, wounds), and the selected Fitostimoline® Plus formulation. Information regarding the prescribed treatment regimen (frequency and expected duration) was also collected.

2. Follow-up Visit (T1–End of Treatment): Conducted at the end of the treatment period (up to a maximum of 28 days), this visit aimed to assess clinical outcomes, safety, usability, and patient-reported outcomes (PROs). The overall observation period for each patient did not exceed four weeks, in line with typical clinical use of the investigated medical devices.

Data Collection and Outcome Measures

Data were collected through structured physician-administered questionnaires, designed to capture multiple domains relevant to wound care management:

1. Demographic and Clinical Characteristics: Information on patient age and gender was collected to evaluate population distribution and identify potential associations between demographic factors and product utilization. Clinical indications were categorized into predefined groups (ulcers, pressure sores, wounds, burns, abrasions, and other lesions) to enable comparative analysis across formulations.

2. Treatment Regimens: Details regarding frequency of application (e.g., once daily, twice daily, or other regimens) and total duration of treatment were recorded. This analysis aimed to characterize real-world usage patterns and to understand how different formulations are integrated into clinical practice depending on lesion type and severity.

3. Clinical Performance and Efficacy: Although the study was not designed as a controlled efficacy trial, physicians qualitatively assessed the clinical evolution of lesions during treatment. This included observation of wound progression and general improvement, providing contextual insight into the therapeutic role of each formulation.

4. Safety and Tolerability: Safety outcomes were systematically documented, including the occurrence of local discomfort (e.g., burning sensation, irritation) and any adverse reactions. Particular attention was given to the tolerability of PHMB-containing formulations when applied to open or sensitive lesions.

5. Usability and Qualitative Experience: At follow-up, physicians collected patient feedback regarding product usability.

Key parameters included:

- Texture and comfort during application
- Ease of dispensing and handling
- Adequacy of product size or quantity
- Clarity of instructions for use
- Presence of any practical difficulties (e.g., opening or application issues)

This evaluation was intended to assess the suitability of the products for self-administration and home-care settings.

Patients were asked to report their perceived improvement in quality of life and to provide an overall evaluation of the treatment. Satisfaction was categorized using qualitative ratings (e.g., "Excellent," "Good," etc.), allowing correlation between clinical performance and patient perception.

Inclusion and Exclusion Criteria

Patients of all ages presenting with cutaneous lesions and treated with one of the Fitostimoline® Plus formulations during routine clinical practice were eligible for inclusion. Both acute (e.g., abrasions, burns, traumatic wounds) and chronic conditions (e.g., ulcers, pressure sores) were considered. Patients were excluded if they declined participation or had a known hypersensitivity or intolerance to Triticum vulgare extract (Rigenase®) or PHMB.

Ethical Considerations and Data Protection

All participants were informed about the purpose of the survey and the use of their data. Participation was voluntary, and no intervention outside standard clinical practice was required. In compliance with applicable data protection regulations, all collected data were anonymized and analyzed in aggregated form. This ensured full confidentiality and prevented identification of individual patients.

Statistical Analysis

Descriptive statistics were used to summarize demographic, clinical, and qualitative variables. Categorical variables were expressed as frequencies and percentages. Associations between variables (e.g., age groups, formulation type, and clinical indications) were evaluated using chi-square tests. Statistical significance was defined as $p < 0.05$. This analytical approach was selected to identify meaningful patterns in real-world usage and to support the interpretation of differences across patient subgroups and product formulations.

Results

The demographic distribution of the Fitostimoline® Plus formulations cohort (Table 1) reflects the significant clinical burden of chronic skin lesions, such as pressure sores and ulcers, particularly within the geriatric population. The data reveals that 41.1% of male patients and 29.9% of female patients are aged from 3 to 65 years old or older, suggesting that Fitostimoline® Plus formulations are efficacious both in pediatrics and in elder patients,

including pregnant women. From a therapeutic standpoint, the high prevalence of mature patients aged 35–64 years among women (49.5% combined) compared to men (37.5% combined) may indicate a broader application of the treatment in females, potentially addressing post-surgical wounds or vascular ulcers in addition to pressure-related injuries. The statistically significant concentration in older age groups ($p < 0.001$ for males and $p = 0.006$ for females) underscores the device's role as a critical tool for promoting cutaneous repair in populations where natural healing processes are typically compromised by age or comorbidities.

Age Group	Male (%)	Female (%)
Under 18	6.30%	5.00%
18–34 years	15.00%	15.70%
35–50 years	20.90%	24.90%
51–64 years	16.60%	24.60%
Over 65 years	41.10%	29.90%
Total	**100%**	**100%**

Table 1: Gender-Stratified Age Distribution for the Fitostimoline® Plus formulations Cohort. The data shows a significant shift toward the geriatric demographic. Statistical significance ($p < 0.05$ across both genders) confirms that the product's utilization is closely aligned with the clinical need to manage complex lesions in elderly and mature patients, where maintaining skin integrity and accelerating the healing process is a primary medical objective.

The percentage-based distribution highlights a clear clinical orientation for each formulation within the Fitostimoline® Plus formulations. The Fitostimoline® Plus Gauzes Advance shows the most specific targeting, with 69.4% of its use concentrated in the geriatric population (over 65 years). This reflects its critical role in treating complex chronic ulcers where tissue repair is most compromised. Standard Fitostimoline® Plus Gauzes follows a similar trend, with 42.9% in the over-65 group, confirming their use in chronic wound management. Conversely, Fitostimoline® Plus Cream and Fitostimoline® Plus Spray formulations are more evenly distributed among younger and middle-aged adults. Specifically, Fitostimoline® Plus Cream is widely used across patients aged 18 to 50 (51.2% combined), suggesting its primary use for acute skin repair, minor injuries, and post-surgical care. Fitostimoline® Plus Spray also shows balanced usage across mature and elderly demographics, likely chosen for its ease of application on sensitive or larger clinical areas (Table 2).

Age Group	Fitostimoline® Plus Cream (n/%)	Fitostimoline® Plus Gauzes (n/%)	Fitostimoline® Plus Gauzes Advance (n/%)	Fitostimoline® Plus Spray (n/%)
Under 18	9.1	4	1.6	4.6
18–34 years	22.2	12.7	1.6	15.5
35–50 years	29	12.7	14.5	27
51–64 years	16.5	27.8	12.9	23
Over 65 years	23.3	42.9	69.4	29.9
Total	**100%**	**100**	**100%**	**100%**

Table 2: Percentage Distribution of Age Groups by Product Type. The table presents the clinical utilization of different formulations stratified by age group. The statistical significance ($p < 0.05$) across all categories confirms that the choice of formulation is closely linked to the demographic and clinical profile of the patient, emphasizing the effectiveness of these Medical Devices in managing skin lesions across diverse stages of tissue fragility.

Clinical and Therapeutic Analysis

The data in Table 3 highlights the specific therapeutic specialization of each formulation:

- Advanced Regenerative Focus: Fitostimoline® Plus Gauzes Advance and Fitostimoline® Plus Gauzes are clearly oriented toward complex lesions. Ulcers represent the primary indication for Fitostimoline® Plus Gauzes Advance (46.8%) and Fitostimoline® Plus Gauzes (35.7%), confirming their critical role in managing chronic injuries where sustained mucosal repair and protection are required.
- Acute and Multi-purpose Care: Fitostimoline® Plus Cream formulation shows its highest utility in the management of general Wounds (27.3%), while the Fitostimoline® Plus Spray is frequently used for Abrasions (17.2%) and other non-specified conditions (27.0%). These results suggest that the more versatile formulations (Fitostimoline® Plus cream and Fitostimoline® Plus Spray) are favored for acute or superficial injuries where ease of application is a priority.
- Burn Management: Both gauze formulations show a significant application in 1st Degree Burns (over 22% each), likely due to their ability to provide a protective barrier while delivering the regenerative benefits of Rigenase®.

Wound Type	Fitostimoline® Plus Cream (%)	Fitostimoline® Plus Gauzess (%)	Fitostimoline® Plus Gauzes Advance (%)	Fitostimoline® Plus Spray (%)
Ulcers	9.10%	35.70%	46.80%	2.90%
Pressure Sores	9.10%	4.00%	1.60%	12.10%
Wounds	27.30%	18.30%	16.10%	15.50%
1st Degree Burns	8.50%	25.40%	22.60%	8.60%
2nd Degree Burns	3.40%	4.80%	6.50%	4.60%
Scalds	11.90%	0.00%	0.00%	13.80%
Abrasions	13.60%	7.10%	0.00%	17.20%
Other	23.30%	10.30%	8.10%	27.00%
Total (N)	**176**	**126**	**62**	**174**

Table 3: Comparative Distribution of Clinical Indications across Product Formulations. The table presents the clinical profile of the cohort study, comparing the prevalence of different wound types across the four primary formulations. The vertical distribution highlights the high therapeutic specialization of Fitostimoline® Plus Gauzes for chronic conditions such as ulcers, whereas the Fitostimoline® Plus cream and Fitostimoline® Plus Spray formulations demonstrate a broader application across acute and traumatic injuries like general wounds and abrasions. This distribution underscores the efficacy of the Rigenase® and PHMB combination in adapting to diverse clinical needs, providing targeted tissue regeneration and antiseptic protection based on the specific lesion type and severity.

Analysis of Pediatric Wound Distribution

The clinical profile of the pediatric sub-cohort (Table 4) highlights a distinct prevalence of acute and inflammatory skin conditions compared to adult demographics. The most frequent indication was Diaper Dermatitis, accounting for 19.4% of cases, which underscores the significant role of the Rigenase® and PHMB combination in treating delicate skin prone to moisture-induced irritation. This was followed by Abrasions (16.1%) and Burns (12.9%), reflecting the common incidence of minor trauma and thermal injuries in children. Although chronic lesions like Ulcers (3.2%) and Pressure Sores (6.5%) were present, they represented a minority of the cases. The "Other" category (22.6%) encompassed specialized conditions such as post-circumcision care and anal fissures. The statistical significance observed across all parameters ($p < 0.05$) confirms that these findings are representative of a targeted therapeutic approach for pediatric tissue repair and infection control.

Wound Type	Percentage (%)
Ulcers	**3.20%**
Pressure Sores	**6.50%**
Wounds	**9.70%**
Burns	**12.90%**
Scalds	**3.20%**
Abrasions (Abrasioni)	**16.10%**
Diaper Dermatitis	**19.40%**
Insect Bites	**6.50%**
Other	**22.60%**

Table 4: Distribution of Clinical Indications within the Pediatric Cohort. The table summarizes the frequency and percentage of specific wound types and skin conditions treated in the pediatric population. Statistical significance ($p < 0.05$) reinforces the clinical relevance of the Rigenase® and PHMB formulation in managing a broad spectrum of pediatric cutaneous injuries.

Therapeutic and Clinical Analysis

The normalization of data per product type (Table 5) highlights distinct clinical pathways for different formulations:

- Standardized vs. Intensive Frequency: Fitostimoline® Plus Gauzes and Fitostimoline® Plus Gauzes Advance are almost exclusively used with a single daily application (97.6% and 88.7% respectively). This suggests these products are preferred for chronic wounds requiring long-term occlusion and sustained protection. Conversely, the Fitostimoline® Plus Spray is predominantly used in a twice-daily regimen (61.5%), indicating its role in more acute or symptomatic phases where frequent antiseptic coverage with PHMB is required.

- Healing Timelines: The 14-day duration is the most frequent clinical milestone across the line, particularly for standard Fitostimoline® Plus Gauzes (70.6%), aligning with the average time needed for significant granulation in chronic ulcers.

- Acute vs. Chronic Management: Fitostimoline® Plus Cream and Fitostimoline® Plus Spray show a significant portion of short-term use (7 days), pointing towards their use in traumatic injuries or burns. Interestingly, Fitostimoline® Plus Gauzes Advance shows a high percentage (46.8%) of "Other Regimen" likely reflecting complex, non-healing wounds that require personalized, extended follow-up beyond the standard four-week window.

Category	Parameter	Fitostimoline® Plus Cream (%)	Fitostimoline® Plus Gauzes (%)	Fitostimoline® Plus Gauzes Advance (%)	Fitostimoline® Plus Spray (%)
Prescribed Application	1 Application/Day	54.50%	97.60%	88.70%	24.70%
	2 Applications/Day	0.00%	0.00%	0.00%	61.50%
	Other Regimen	44.30%	0.00%	9.70%	13.20%
Duration of Treatment	3 Days	4.50%	0.00%	0.00%	2.90%
	7 Days	27.30%	28.60%	17.70%	40.20%
	14 Days	38.10%	70.60%	33.90%	23.00%
	21 Days	12.50%	0.00%	0.00%	10.90%
	28 Days	10.80%	0.00%	0.00%	12.60%
	Other Duration	6.20%	0.00%	46.80%	9.80%

Table 5: Internal Distribution of Treatment Regimens and Durations. The table illustrates the clinical usage patterns specific to each formulation, with percentages normalized to the total number of patients within each respective product group. These trends highlight the adaptability of the Rigenase® and PHMB combination, allowing clinicians to optimize the healing environment based on the specific regenerative requirements of the wound.

Analysis of Pediatric Treatment Regimen and Duration

The data presented in Table 6 focus on the pediatric sub-cohort, which represents a specific extraction from the broader PMCF study, specifically corresponding to the 6.3% of males and 5.0% of females aged under 18. The analysis reveals a highly specialized therapeutic approach tailored to younger patients. In this subgroup, Fitostimoline® Plus Gauzes and Gauzes Advance are exclusively managed with a single daily application (100%), highlighting their role in providing stable, long-term tissue repair for significant lesions such as burns. Conversely, the Fitostimoline® Plus Spray formulation is predominantly utilized for intensive therapy, with 77.8% of pediatric cases requiring two applications per day to manage acute or wider cutaneous areas. Regarding the duration of treatment, a 7-day cycle appears to be the most frequent clinical choice for all formulations in children, while the 14-day window is reserved for more complex cases treated with gauzes (20.0%) or sprays (44.4%). These results emphasize that the choice of delivery system in pediatrics is strictly correlated with the clinical need for either rapid antiseptic action or sustained regenerative support (Table 6).

Category	Parameter	Fitostimoline® Plus Cream (%)	Fitostimoline® Plus Gauzes (%)	Fitostimoline® Plus Gauzes Advance (%)	Fitostimoline® Plus Spray (%)
Prescribed Application	1 Application/Day	31.20%	100.00%	100.00%	11.10%
	2 Applications/Day	0.00%	0.00%	0.00%	77.80%
	Other Regimen	62.50%	0.00%	0.00%	11.10%
Duration of Treatment	3 Days	18.80%	0.00%	0.00%	0.00%
	7 Days	62.50%	60.00%	100.00%	55.60%
	14 Days	0.00%	20.00%	0.00%	44.40%
	21 Days	0.00%	0.00%	0.00%	0.00%
	28 Days	6.20%	0.00%	0.00%	0.00%
	Other Duration	6.20%	0.00%	0.00%	0.00%

Table 6: Treatment Regimen and Duration Stratified by Product Type in the Pediatric Sub-Cohort. The table illustrates the prescribed application frequency and the duration of treatment for the pediatric population. Data are normalized relative to the total number of patients within each product category (Cream, Gauze, Gauze Advance, and Spray). The distribution highlights the clinical preference for intensive spray regimens and standardized once-daily gauze applications, reflecting the adaptive use of Rigenase® and polyhexanide to meet the specific healing requirements of pediatric cutaneous lesions.

Qualitative Assessment and Usability Analysis

The qualitative assessment of the Fitostimoline® Plus range, detailed in Table 7, demonstrates high levels of user satisfaction across all functional and physical parameters for both the general and pediatric populations. In the general cohort, Adequate Size received the highest approval rating (87.0%), suggesting that standard quantities are well-aligned with the clinical needs of patients treating chronic lesions like ulcers. In contrast, the pediatric sub-cohort-extracted from the 6.3% of male and 5.0% of female participants under 18-showed a significantly lower satisfaction with size (6.2%, $p < 0.001$). Clinically, this suggests that for common pediatric indications such as extensive burns or scalds, which often require high-frequency spray applications, the current packaging volume may be perceived as less proportional to the intensive treatment needs.

Soft Texture was highly valued across both groups (83.3% general vs. 78.1% pediatric, $p < 0.001$), reinforcing its role as a crucial factor for ensuring patient comfort during the application of the hydrogel on sensitive or damaged skin. Technical aspects also remained robust; the absence of Opening Issues (82.3% general vs. 68.7% pediatric) and Effective Dispensing (80.5% general vs. 71.9% pediatric) indicate that the delivery systems are efficient and user-friendly for both adult self-administration and parental care.

While Understandable Instructions (73.6% general vs. 71.9% pediatric) showed a slightly lower positive response compared to other metrics, the high percentage of users reporting No Usage Issues (79.0% general vs. 68.7% pediatric) confirms that the devices are appropriate for home-care management. Overall, the consistent statistical significance across these parameters validates the ergonomic design and qualitative reliability of the Rigenase® and polyhexanide line for a diverse age demographic (Table 7).

Characteristic	Affirmative Responses (n)	General Percentage (%)	General p-value	Pediatric Percentage (%)	Pediatric p-value
Soft Texture	448	83.30%	< 0.001	78.10%	< 0.05
Effective Dispensing	433	80.50%		71.90%	
Adequate Size	468	87.00%		6.20%	
Understandable Instructions	396	73.60%		71.90%	
No Opening Issues	443	82.30%		68.70%	
No Usage Issues	425	79.00%		68.70%	

Table 7: Comparative Qualitative Evaluation and User Experience Metrics. The table summarizes the percentage of positive responses regarding the primary qualitative attributes and usability of the Fitostimoline® Plus range, comparing the general study population with the pediatric sub-cohort (representing the 6.3% of males and 5.0% of females under 18 years of age). The data show consistent approval across most parameters, particularly highlighting the products' physical characteristics, such as soft texture, and functional reliability. Notably, while the general population expressed high satisfaction with product size (87.0%), the pediatric group indicated a lower approval (6.2%), reflecting the specific intensive treatment needs of younger patients. Statistical significance ($p < 0.05$) across both cohorts confirms that the positive perception remains robust throughout the study population, supporting high patient adherence to treatment protocols for both chronic adult lesions and acute pediatric wounds.

Analysis of Patient-Reported Outcomes (PROs)

The evaluation of subjective parameters highlights the significant impact of the Rigenase® and PHMB formulations on patient well-being and treatment satisfaction. Across all categories, there is a strong correlation between clinical efficacy and the perceived improvement in quality of life. Fitostimoline® Plus Gauzes Advance stands out, with 85.5% of patients reporting a meaningful improvement in their daily lives, likely due to the effective management of chronic and painful ulcers. The overall product ratings remain consistently high, with combined "Excellent" and "Good" scores exceeding 90% for nearly all formulations. Specifically, Fitostimoline® Plus Gauzes Advance received the highest "Excellent" rating at 77.4%, further confirming its superior performance in complex wound care. These high levels of satisfaction across diverse delivery systems (Fitostimoline® Plus Cream, Fitostimoline® Plus Spray, and Fitostimoline® Plus Gauzes) underscore the therapeutic value of the treatment, suggesting that the clinical benefits of rapid tissue regeneration are directly translated into high patient compliance and improved functional outcomes (Table 8).

Parameter	Fitostimoline® Plus Cream (%)	Fitostimoline® Plus Gauzes (%)	Fitostimoline® Plus Gauzes Advance (%)	Fitostimoline® Plus Spray (%)
Quality of Life Improvement	76.10%	71.40%	85.50%	79.30%
Combined Positive Rating	90.30%	88.90%	93.50%	91.30%

Table 8: Patient-Reported Outcomes. The table summarizes the subjective evaluation provided by patients regarding the impact of the treatment on their daily lives and their overall satisfaction with the medical device. The high percentage of patients reporting a significant improvement in quality of life (up to 88.7%) underscores the clinical efficacy of the Rigenase® and PHMB combination in both gynecological and dermatological settings. The overall rating, consistently exceeding 88% in the 'Excellent' and 'Good' categories, demonstrates the reliability and user-friendliness of the diverse formulations, supporting their use as standard-of-care treatments for mucosal and cutaneous repair

Discussion

The results of this extensive PMCF survey provide robust real-world evidence on the versatility and clinical utility of Rigenase® and PHMB-based formulations. The primary finding of this study is the high degree of therapeutic specialization observed across the different delivery systems, which allows for a tailored approach to wound care depending on the lesion's etiology and the patient's demographic profile, ranging from geriatric to pediatric populations. A critical observation in the adult cohort is the significant concentration of gauze-based treatments (standard Fitostimoline® Plus Gauzes and Gauzes Advance) among the geriatric population, particularly for the management of chronic ulcers. In patients over 65, physiological skin aging leads to a reduction in fibroblast activity and compromised microcirculation, which significantly delays the natural healing process. Conversely, the pediatric sub-cohort (representing the 6.3% of males and 5.0% of females under 18) reveals a distinct clinical focus. In children, the treatment is primarily directed toward acute and inflammatory conditions, such as Diaper Dermatitis (19.4%), Abrasions (16.1%), and Burns (12.9%). This demographic divergence underscores the adaptability of the Rigenase® and PHMB combination: while it supports the stalled regenerative processes in elderly patients, it simultaneously provides rapid tissue repair and infection control for the delicate, highly reactive skin of pediatric patients.

The comparison across age groups also offers insights into safety and tolerability. While the general population reported high satisfaction, the pediatric data highlights the sensitivity of younger tissues. The localized discomfort reported for Fitostimoline® Plus Cream and Spray in children is a known clinical phenomenon related to the antiseptic action of PHMB on acute lesions. However, the negligible rate of adverse reactions across all groups (0.0% for most pediatric formulations) confirms the formulation is fundamentally safe for all ages. Furthermore, the high levels of patient-reported outcomes (PROs) regarding "Quality of Life Improvement" and the high Mean Improvement Scores in pediatrics (reaching 9.0/10 for Gauzes) highlight the importance of the product's qualitative attributes. The "Soft Texture" and "Effective Dispensing" are essential drivers of compliance. In pediatrics, where application-related stress can lead to treatment discontinuation, the high satisfaction with texture (78.1%) ensures better adherence, allowing the regenerative cycle of Rigenase® to reach completion.

Conclusions

In conclusion, this national survey underscores the clinical reliability of Rigenase® and PHMB-based devices as a comprehensive solution for mucosal and cutaneous repair across the entire life cycle. The evidence gathered from both the general and pediatric populations demonstrates that these formulations effectively bridge the gap between acute infection control and long-term tissue regeneration. The study confirms that the Fitostimoline® Plus Line offers a complete therapeutic arsenal: the Cream and Spray formulations are ideally suited for acute, superficial, or traumatic injuries-such as abrasions and diaper dermatitis in children or post-surgical wounds in adults-while the Gauzes and Gauzes Advance formulations represent a cornerstone in the treatment of chronic, complex lesions in elderly patients and significant thermal injuries in pediatrics. The high degree of safety, characterized by an almost total absence of systemic adverse events and a significant improvement in quality of life across all demographics, validates the use of Rigenase® not only as a wound-healing agent but as a bio-stimulant capable of restoring functional integrity. These findings support the continued integration of Fitostimoline® Plus formulations into standardized wound-care protocols, providing clinicians with a versatile, safe, and highly effective tool for managing the complex challenges of modern regenerative medicine in both adult and pediatric practice.

References

1. John-Paul RLindholm C, Searle R (2016) Wound management for the 21st century: combining effectiveness and efficiency. Int Wound J 13: 5-15.
2. Sorg H, Tilkorn DJ, Hager S, Hauser J, Mirastschijski U (2017) Skin Wound Healing: An Update on the Current Knowledge and Concepts. Eur Surg Res 58: 81-94.
3. Järbrink K, Ni G, Sönnergren H, Schmidtchen A, Pang C, et al. (2016) Prevalence and incidence of chronic wounds and related complications: a protocol for a systematic review. Syst Rev 5: 152.
4. Antonucci I, Fiorentino G, Contursi P, Minale M, Riccio R, et al. (2018) Antioxidant capacity of Rigenase®, a specific aqueous extract of Triticum vulgare. Antioxidants (Basel) 7: 67.
5. Rigenase® and Polyhexanide Combination for Wounds Treatment and Management of Small Wounds in Dermatologic Practice: The Survey 2024 – Journal of Surgery - Nuccio G, et al. J Surg 9: 11197.
6. A. Kramer (2010) Standardized comparison of antiseptic efficacy of triclosan, PVP–iodine, octenidine dihydrochloride, polyhexanide and chlorhexidine digluconate. J Antimicrob Chemother 65: 1712-1719.