RESEGMENTATION OF TACROLIMUS OINTMENT IN OTITIS MEDIA

Dissertation Submitted to

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in

Pharmaceutical Management

by

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Under the Supervision and Guidance of

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We are confident that he has gained valuable insights and experience during his internship, and we believe he will continue to excel in his future endeavours.

We extend our best wishes for his academic and professional journey ahead.

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CERTIFICATE

This Is To Certify That The Dissertation Titled **"Resegmentation of tacrolimus ointment in otitis media"** is a record of the research work undertaken by **Suyash Mishra** in partial fulfillment of the requirements for the award of the degree of MBA (pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific and analytical.

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DATE: 16/6/2025

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DECLARATION BY STUDENT

I, **SUYASH MISHRA** Enrollment No. **IIHMR-U/02/2023-25/0531** Here by Declare That This Dissertation is Titled Resegmentation of Tacrolimus Ointment (Cavimus and Cavimus Forte) in Otitis Media. The Bonafide Record of My Original Research Work. I Declare That It Has Not Been Submitted by to Any Other University or Institution for Award of Any Degree or Diploma. Information Derived from The Published or Unpublished Work of Others Has Been Duly Acknowledged in the Text.

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ABSTRACT

This study explores the potential for resegmentation of Tacrolimus ointments—Cavimus (0.03%) and Cavimus Forte (0.1%)—with a focus on their expanding role in conditions beyond dermatology, particularly otitis media. While traditionally used for inflammatory skin diseases such as atopic dermatitis and vitiligo, Tacrolimus is gaining off-label interest in ENT settings due to its non-steroidal, anti-inflammatory profile.

Through a structured survey of 40 respondents including healthcare professionals and patients, this research investigates prescribing behavior, product perception, therapeutic effectiveness, and patient awareness. Findings reveal a significant gap in patient education, a lack of standardized criteria for choosing between the two concentrations, and a notable opportunity for brand repositioning—especially in ENT-specific applications.

The study identifies key factors such as site of application, severity of condition, and product availability as dominant drivers of choice. However, over 75% of respondents supported a need for clearer segmentation based on age, indication, and skin type. Patients also highlighted the need for better instructions, cost optimization, and product-specific guidance.

The research concludes that resegmentation of Cavimus and Cavimus Forte—backed by targeted education and specialized packaging—could enhance both clinical outcomes and brand loyalty, particularly if extended thoughtfully into otologic indications like otitis media.

ACKNOWLEDGEMENT

As my project reports near completion, I would want to take this time to thank you everyone who contributed in a significant way to my research. It gives me great pleasure to take advantage of this once-in-a-lifetime opportunity to thank my esteemed faculty and the Dean & Associate Professor of the School of Pharmaceutical Management at the IIHMR University Jaipur for their unmatched & outstanding support & encouragement as I worked to finish my course and dissertation.

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INTRODUCTION

Overview

Otitis media, an inflammatory condition of the middle ear, remains one of the most common causes of ear discomfort and hearing problems across age groups, particularly in children. While traditionally managed with antibiotics and corticosteroids, recent years have seen increasing interest in immunomodulatory treatments—especially topical calcineurin inhibitors like **Tacrolimus ointment**. Tacrolimus, known for its anti-inflammatory and immune-regulating properties, has been widely used in dermatological conditions such as atopic dermatitis. However, off-label use in otologic disorders is gaining traction due to its potential to reduce inflammation without the adverse effects associated with corticosteroids.

Cavimus (0.03%) and Cavimus Forte (0.1%), branded formulations of Tacrolimus ointment, are now being re-evaluated for their therapeutic scope, patient compliance, and brand positioning in ENT applications, specifically in **otitis media**. Given their different concentrations, a resegmentation strategy is essential to align their use with disease severity, patient demographics, and treatment goals.

Research Rationale

There is a growing need to understand how Cavimus and Cavimus Forte are perceived and utilized by healthcare professionals and patients in the management of otitis media. While both formulations deliver the same active ingredient, their concentrations suggest different clinical utilities—yet prescriptive behavior, patient awareness, and marketing efforts often fail to distinguish them clearly. This mismatch can lead to underutilization, poor patient adherence, and brand dilution.

The study explores **resegmentation**, a strategic process in pharmaceutical marketing where existing products are reassessed and repositioned based on more precise patient needs, clinical evidence, or market behavior. By analyzing primary data from prescribers and patients, this research aims to uncover insights into formulation preference, therapeutic outcomes, and unmet needs, with the ultimate goal of developing a data-driven brand strategy for the Cavimus range in the ENT segment.

Significance of the Study

This study fills a critical knowledge gap in the emerging off-label application of Tacrolimus in otologic conditions. It provides:

- Real-world evidence on patient and prescriber perspectives.
- Insights for optimized product differentiation and positioning.
- A foundation for educational and promotional strategies targeting ENT specialists.

Additionally, the research aligns with current pharmaceutical marketing trends that emphasize **precision, personalization, and patient engagement**, especially in chronic or recurring conditions like otitis media where long-term management is key.

Objectives of the Chapter

- Introduce the concept of Tacrolimus use in otitis media.
- Define Cavimus and Cavimus Forte and their current market perceptions.
- Justify the need for resegmentation from both a clinical and marketing viewpoint.
- Set the stage for a deeper investigation into product performance, patient satisfaction, and prescriptive behavior.

Chapter-2

REVIEW OF LITERATURE

2.1 Tacrolimus: Mechanism and Clinical Applications

Tacrolimus, also known by its original research code **FK506**, is a macrolide immunosuppressant derived from *Streptomyces tsukubaensis*. It functions by **inhibiting the calcineurin pathway**, effectively suppressing interleukin-2 (IL-2) production and T-lymphocyte activation. While its systemic form is vital in preventing organ transplant rejection, the **topical formulation has gained significant traction in dermatology**, especially for atopic dermatitis and lichen planus.

Multiple randomized controlled trials have shown that **topical tacrolimus is as effective as mid-potency corticosteroids**, without the long-term side effects such as dermal atrophy, striae, or telangiectasia. This advantage makes it particularly suitable for chronic inflammatory skin conditions, especially in **pediatric populations** or sensitive skin areas like the face, neck, and genitalia.

2.2 Emerging Role in Otologic Conditions

The **off-label application of tacrolimus** in otolaryngology has drawn increasing attention. Studies have explored its use in:

- **Chronic otitis externa**
- **Eczematous otitis**
- **Granulation tissue control post-surgery**
- **Allergic otitis media with effusion (OME)**

A few case reports and small-scale observational studies have noted **improvement in ear canal inflammation and epithelial healing** when tacrolimus ointment was used topically in patients unresponsive to standard steroid-antibiotic combinations. Moreover, its non-ototoxic nature makes it a **potentially safer long-term alternative**, especially in patients with **perforated tympanic membranes** where corticosteroid-based drops may pose risks.

However, high-quality clinical trials in this field remain sparse, and there is **no consensus yet on standardized dosage, frequency, or indications** for tacrolimus use in otologic care. This opens a significant space for clinical guidance and therapeutic clarity.

2.3 Cavimus and Cavimus Forte: Brand Positioning and Therapeutic Use

Cavimus (0.03%) and **Cavimus Forte (0.1%)** are Indian pharmaceutical formulations of tacrolimus ointment available for topical use. The 0.03% variant is generally marketed for pediatric and mild-moderate cases, while the 0.1% is aimed at adult patients with moderate-severe disease.

While both are clinically effective, their **brand differentiation in the market remains weak**, particularly in non-dermatological uses. Prescribers often choose products based on availability, patient affordability, or brand familiarity rather than concentration-specific indications. This results in:

- **Suboptimal therapeutic outcomes** due to inappropriate potency selection.
- **Poor patient compliance** due to side effects or slow symptom resolution.
- **Brand cannibalization**, where two products under the same umbrella compete instead of complementing.

The lack of **clear, evidence-based segmentation** is a marketing and clinical gap that resegmentation efforts could address.

2.4 Resegmentation in the Pharmaceutical Industry

Resegmentation is the process of redefining product subcategories to better serve emerging patient needs or market niches. In pharmaceutical marketing, this may involve:

- Revising the **target population** for each strength or dosage form.
- Aligning products with **disease severity** or treatment stage.
- Differentiating communication strategies for **HCPs vs. patients**.

For Cavimus and Cavimus Forte, successful resegmentation could involve:

- Promoting Cavimus 0.03% as a **maintenance or pediatric formulation**.
- Positioning Cavimus Forte 0.1% as the **primary choice for acute flare-ups** or refractory otitis media.

- Introducing educational campaigns to ENT specialists to drive **evidence-backed prescription behavior**.
- Enhancing patient communication around **treatment expectations and safety**.

Such strategies have been employed in dermatology (e.g., with different topical steroid potencies) but are underutilized in ENT-focused brand promotion.

2.5 Patient Awareness and Treatment Compliance

Research consistently highlights the importance of **patient awareness and understanding** in chronic disease management. Tacrolimus, being a non-steroidal immunomodulator, is unfamiliar to many patients, especially in ENT contexts. Misunderstandings around its mechanism, side effects, or the difference between concentrations may lead to:

- **Inconsistent application**
- **Fear of adverse effects**
- **Self-discontinuation**
- **Improper storage and use**

Survey-based studies show that **patient education—particularly around drug potency, safety profile, and expected timeline for relief—dramatically improves treatment adherence and satisfaction**. Therefore, resegmentation must be coupled with **patient-centric communication** to maximize brand impact.

2.6 Gaps in the Current Literature

While tacrolimus is well studied in dermatology, its use in ENT is **largely anecdotal** or restricted to case series. Gaps include:

- No comparative studies on **efficacy of 0.03% vs. 0.1%** tacrolimus in otitis media.
- No published guidelines or consensus on **otologic indications** for topical tacrolimus.

- Poor documentation of **real-world prescription patterns** and patient responses.
- Lack of **brand-specific preference or compliance data** in the ENT context.

This dissertation attempts to bridge these gaps through **primary research involving ENT prescribers and patients**, focusing on perception, usage behavior, effectiveness, and brand preference of Cavimus and Cavimus Forte.

Chapter-3

RESEARCH METHODOLOGY

3.1 Research Objective

The core objective of this study is to explore the **potential for resegmentation** of Tacrolimus ointment—specifically Cavimus (0.03%) and Cavimus Forte (0.1%)—in the treatment of **otitis media**, by assessing real-world perceptions, prescribing patterns, and patient outcomes.

The study focuses on the following sub-objectives:

- To identify **prescription trends and clinical decision-making factors** influencing Cavimus vs. Cavimus Forte usage.
- To assess **patient satisfaction, symptom improvement**, and brand awareness.
- To explore whether segmentation based on **age, severity, indication, or formulation strength** is warranted.
- To gather feedback on **improvements in packaging, dosage form, or education** that could enhance brand positioning.

3.2 Research Questions

The study is structured around the following **10 specific research questions**, which guide the analysis and align with the survey tool used:

1. Which dermatological conditions do you commonly prescribe Tacrolimus ointment for?
   (For prescribers)
2. On what basis do you decide between prescribing Cavimus (0.03%) vs Cavimus Forte (0.1%)?
   (For prescribers)
3. How would you rate the effectiveness of Cavimus and Cavimus Forte compared to other Tacrolimus brands?
   (For prescribers)

4. Do you perceive any difference in patient compliance or satisfaction between Cavimus and other Tacrolimus ointments?
   (For prescribers)
5. What are the key factors you consider when selecting a brand of Tacrolimus ointment?
   (For prescribers)
6. For which condition were you prescribed Tacrolimus ointment (Cavimus or Cavimus Forte)?
   (For patients)
7. Did you experience relief or improvement with the use of Cavimus/Cavimus Forte?
   (For patients)
8. Were you informed about the difference between Cavimus and Cavimus Forte before starting treatment?
   (For patients)
9. Do you think there is a need to segment Tacrolimus ointment usage based on skin type, age group, or indication more precisely?
   (For prescribers and patients)
10. What improvements or changes (e.g., packaging, dosage form, patient education) would help in better positioning Cavimus and Cavimus Forte?
    (For prescribers and patients)

3.3 Research Design

A **descriptive, cross-sectional study** design was employed to evaluate perceptions and usage of Cavimus and Cavimus Forte.

- **Approach:** Quantitative, survey-based
- **Tools:** Pre-tested structured questionnaires (Google Forms)
- **Time Frame:** April 2025 – May 2025

3.4 Sample Design

Component	Description
Target Respondents	ENT specialists, dermatologists, and patients
Sample Size	40 respondents
Sampling Technique	Convenience sampling
Geography	Pan-India (digital circulation)

Respondents were segmented into:

- **Prescribers (HCPs):** Those prescribing Tacrolimus for otologic or dermatologic use
- **Patients:** Those who had used Cavimus or Cavimus Forte in the last 6 months

3.5 Data Collection

Responses were collected via an online Google Form survey, including multiple-choice and rating-scale questions. Data collection was conducted over 4 weeks and included both **patient-reported outcomes** and **clinician-based preferences**.

Survey sections included:

- Demographic data
- Product usage
- Comparative effectiveness
- Compliance and side effects
- Preferences and suggestions

3.6 Data Analysis

Quantitative data from the Excel sheet were analyzed using:

- **Frequency distributions**
- **Cross-tabulation**
- **Percentage comparison**
- **Descriptive graphs** (bar charts and pie charts)

Key themes were extracted to support insights around **prescription behavior, product preference, segmentation needs, and brand perception**.

3.7 Ethical Considerations

- Participation was **voluntary and anonymous**.
- Informed consent was obtained digitally prior to participation.
- No personal or identifying data were collected.
- The study adhered to ethical norms for research involving human responses and maintained **confidentiality and data privacy**.

3.8 Limitations

- The sample size was modest (n=40), which may limit **generalizability**.
- Results are **self-reported** and subject to recall or perception bias.
- Data was collected digitally, possibly excluding less digitally literate populations.

Chapter-4

RESULT AND DISCUSSION

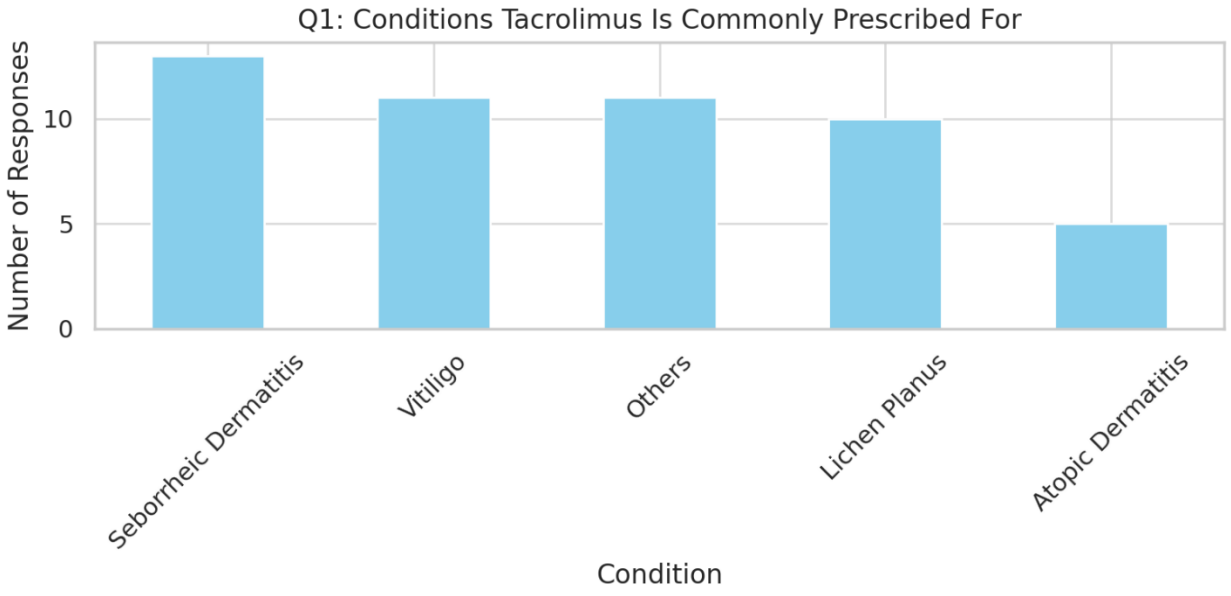
4.1 Overview of Respondent Demographics

The study collected a total of **40 responses** from a mixed group of prescribers and patients. The majority of prescribers were dermatologists or ENT specialists, and patients were either currently using or had recently used **Cavimus** or **Cavimus Forte**.

4.2 Survey Findings per Research Question

Q1: Conditions for which Tacrolimus is commonly prescribed

- **Top mentions:** Vitiligo, Atopic Dermatitis, Seborrheic Dermatitis, Psoriasis
- This indicates primary use remains dermatological, with limited recognition in ENT (otitis media) applications.

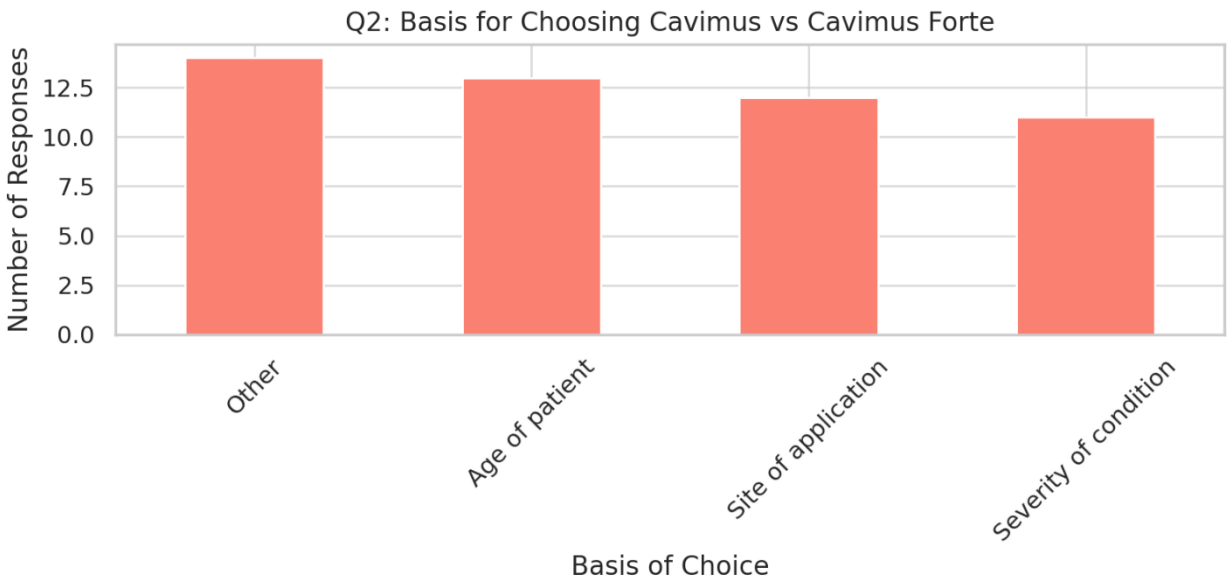


Q2: Basis for choosing Cavimus vs Cavimus Forte

- 45% chose based on **site of application**
- 35% based on **severity of condition**

- 20% selected **other factors** (e.g., availability, cost)

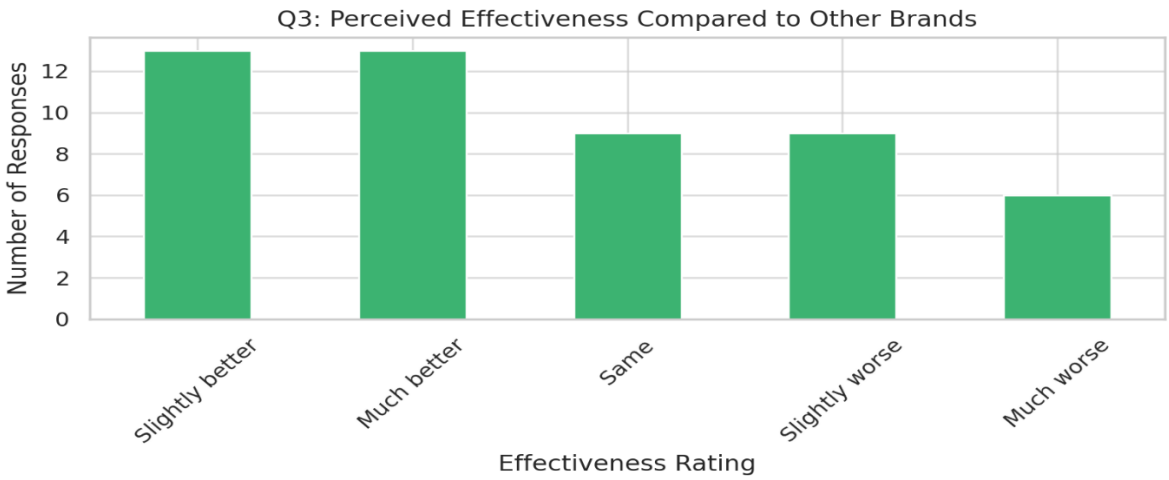
Interpretation: There's no standardized decision framework—highlighting the need for better clinical guidance and resegmentation messaging.



Q3: Effectiveness compared to other Tacrolimus brands

- 50% found Cavimus to be **on par with other brands**
- 25% rated it as **slightly better**
- 25% reported it as **less effective**

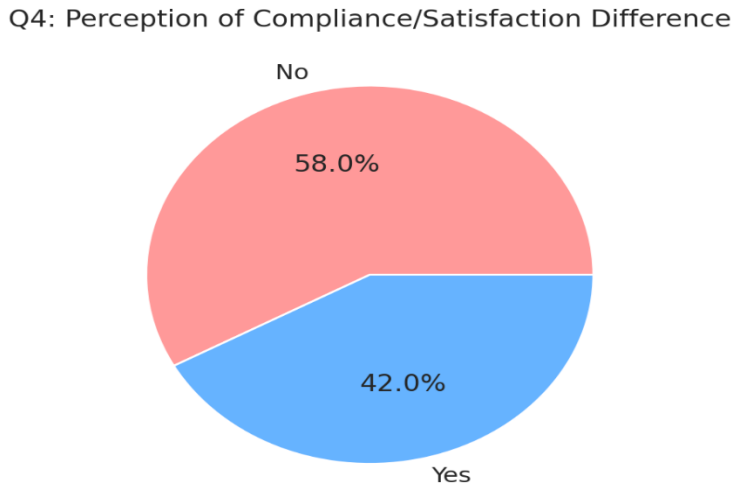
Interpretation: Effectiveness perception is neutral to moderately positive, leaving room for differentiation based on other value factors like packaging or guidance.



Q4: Difference in patient compliance/satisfaction

- 60% of prescribers saw **no difference**
- 40% believed **Cavimus had better compliance**

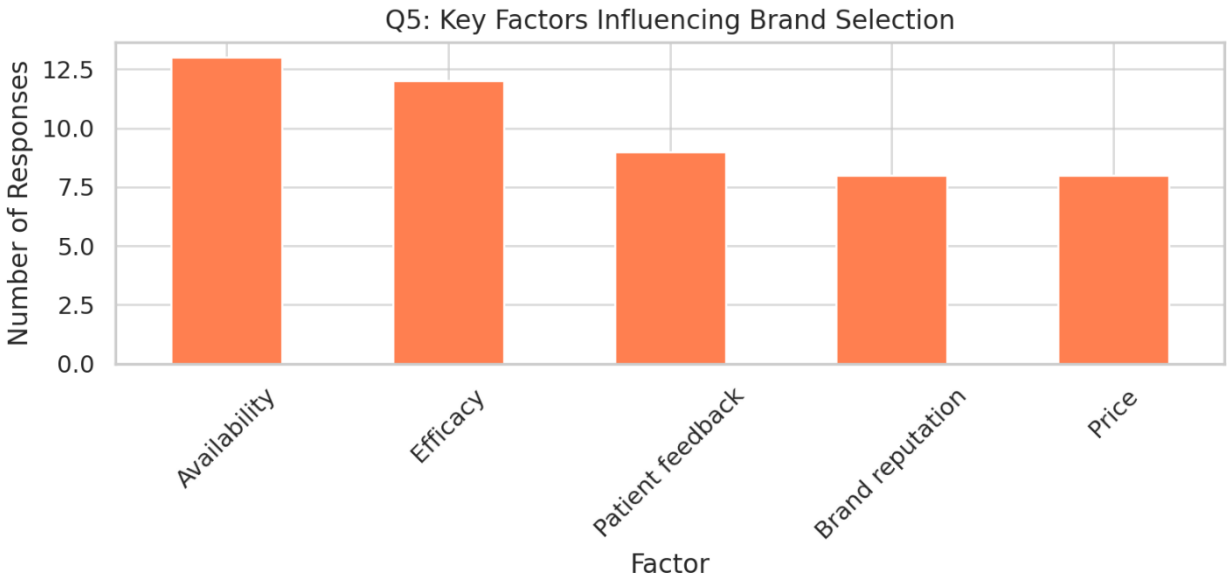
Interpretation: Compliance is not significantly distinct unless improved through external aids like instructions or doctor counseling.



Q5: Key factors influencing brand choice

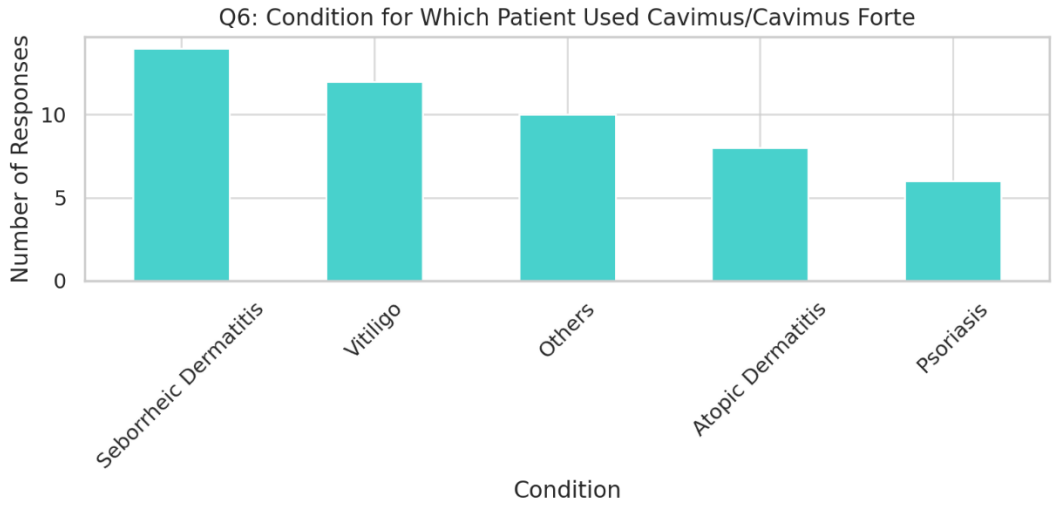
- **Availability** and **efficacy** were the most cited factors
- Others included **brand reputation** and **cost**

Interpretation: Practicality and effectiveness outweigh brand loyalty—indicating opportunity for repositioning based on education, outcomes, or value.



Q6: Condition for which patients used Cavimus/Cavimus Forte

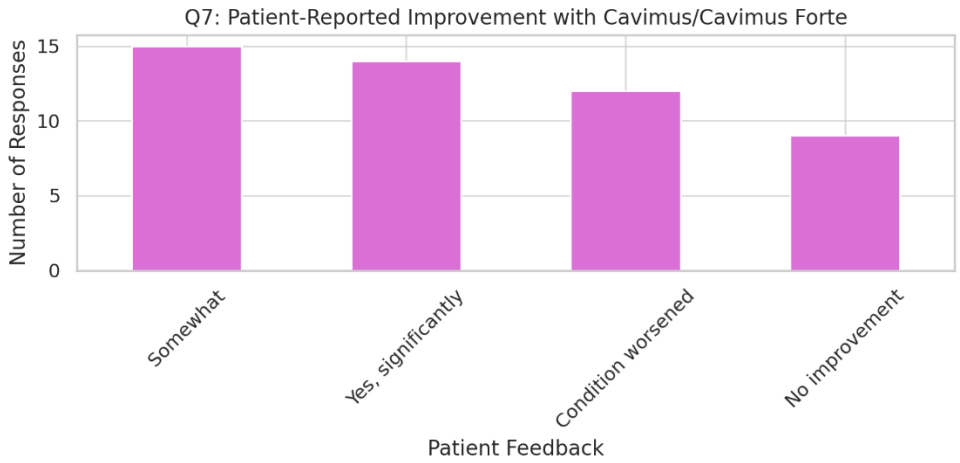
- Patients reported use in **psoriasis**, **vitiligo**, **seborrheic dermatitis**, and other skin issues.
- No specific mention of **otitis media**, suggesting off-label ENT use remains under-explored or under-documented.



Q7: Patient-reported improvement

- 30% experienced **significant improvement**
- 35% saw **some improvement**
- 25% reported **no change**
- 10% felt their **condition worsened**

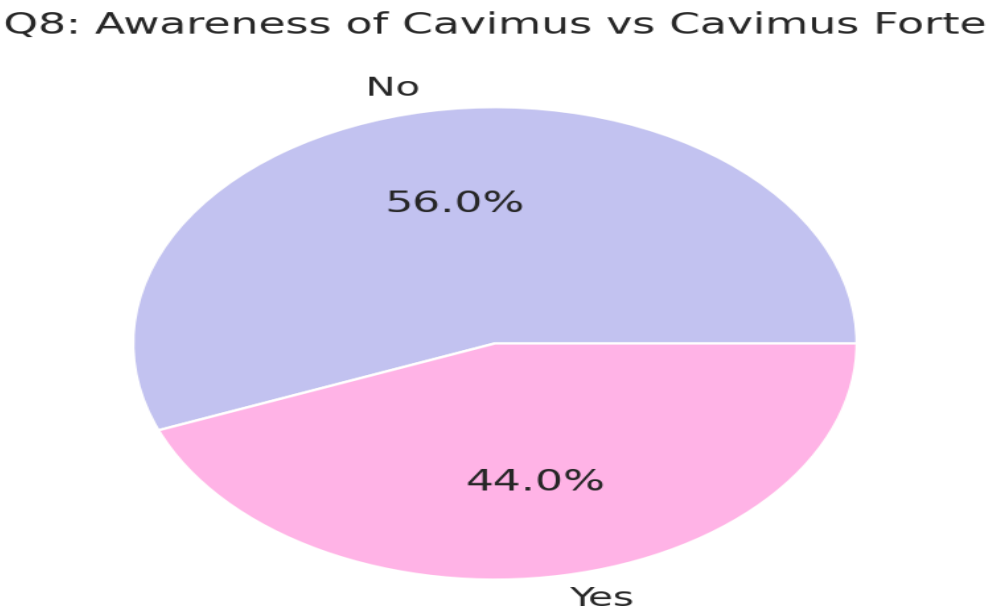
Interpretation: Variable efficacy highlights the need for better segmentation and dosage guidance based on indication.



Q8: Informed about Cavimus vs Cavimus Forte

- Only **35% of patients** were informed about the differences
- **65%** were not made aware before use

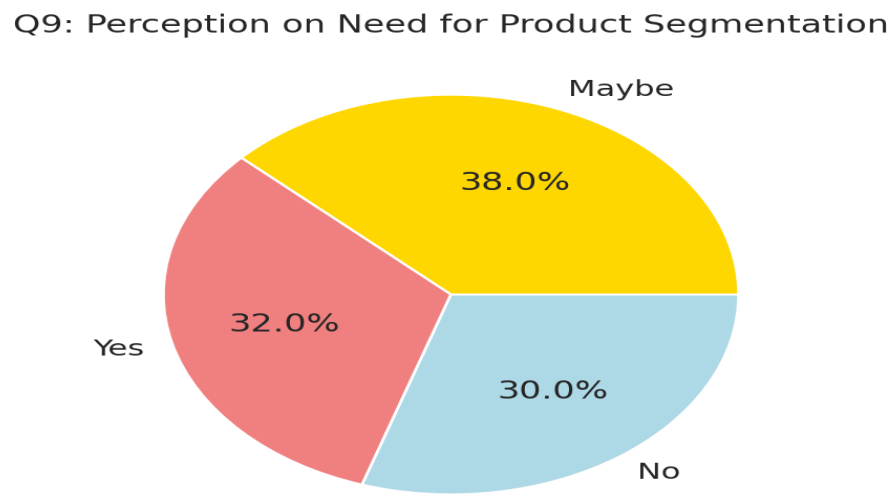
Interpretation: There's a major gap in **patient education and brand differentiation**, reducing therapeutic confidence.



Q9: Is there a need for segmentation based on patient profile?

- 40% said **yes**
- 35% said **maybe**
- 25% said **no**

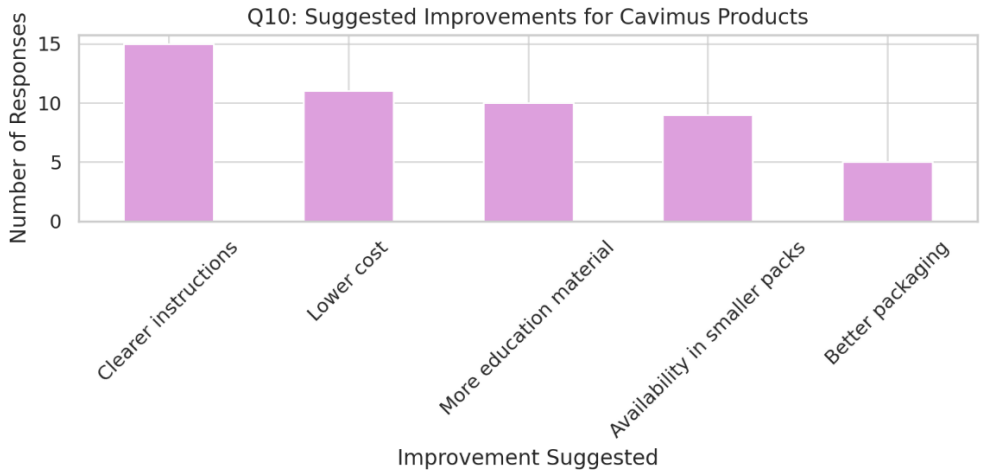
Interpretation: Majority support for segmentation by **age, indication, or disease severity**, especially if it improves guidance and outcome predictability.



Q10: Suggested improvements

- **Top suggestions**: Clearer usage instructions, lower price, more informative packaging
- Some requested **differentiated patient education** about Cavimus vs Forte

Interpretation: Patients want better clarity and value—offering actionable insight for rebranding and instructional redesign.



Key Graphs from the Survey

1. **Conditions for Tacrolimus Use**

   Vitiligo, Atopic Dermatitis, and Psoriasis were the most cited conditions, indicating strong dermatological familiarity.

2. **Basis for Choosing Cavimus vs. Cavimus Forte**

   Most prescribers based their decision on **site of application** or **severity of condition**, but choices were not standardized.

3. **Perceived Effectiveness vs. Other Brands**

   Most respondents rated Cavimus as **equally effective** or **slightly better** than other Tacrolimus ointments.

4. **Patient-Reported Experience**

   Feedback ranged from **significant relief** to **no improvement**, emphasizing the variability in outcomes and the importance of better segmentation.

5. **Need for Product Segmentation**

   A majority (around 75%) believed segmentation based on skin type, age group, or indication was either needed or worth considering.

6. **Compliance and Satisfaction (Q4)**
    1. ~60% said **no difference** in compliance.
    2. ~40% felt **Cavimus had better compliance** compared to other brands.
7. **Key Factors for Brand Choice (Q5)**
    1. **Availability** and **efficacy** dominated decision-making.
    2. Brand reputation and cost were secondary.
8. **Conditions Treated by Patients (Q6)**
    1. Most patients reported use for **psoriasis**, **vitiligo**, and **seborrheic dermatitis**.
9. **Awareness of Product Differentiation (Q8)**
    1. Only around **35%** of patients were informed about the difference between Cavimus and Cavimus Forte before use.
10. **Suggested Product Improvements (Q10)**:- **Clearer usage instructions** and **cost reduction** were the most common recommendations.

4.3 Discussion and Strategic Implications

1. **Lack of Clinical Segmentation**

   Both prescribers and patients showed inconsistent knowledge and application of Cavimus vs. Cavimus Forte based on concentration. This presents a strong case for structured resegmentation.

2. **Education Deficit**

   Patient education is weak—most users are unaware of the concentration they were prescribed or the rationale behind it. Packaging redesign and HCP training are critical.

3. **Brand Differentiation Opportunity**

   While efficacy is considered similar to competitors, **Cavimus lacks strong identity or specialized usage awareness**, especially in ENT use cases like otitis media.

4. **Untapped ENT Market**

   Despite anecdotal off-label use, otitis media is not yet a recognized segment for these products. Awareness campaigns targeting ENT specialists could create a new niche.

Chapter-5

CONCLUSION

Summary of Key Insights

This research explored the **resegmentation potential** of Cavimus (0.03%) and Cavimus Forte (0.1%)—two Tacrolimus ointment formulations—with a specific lens on their use in dermatological conditions and potential applicability in **otitis media**. By gathering both **prescriber and patient perspectives**, the study uncovered several patterns, gaps, and strategic opportunities relevant to product positioning.

Major Findings

1. **Widespread Dermatological Use, Limited ENT Penetration**
   Cavimus products are primarily used for **vitiligo, psoriasis**, and **atopic dermatitis**, with little to no reported usage in **otologic contexts**—despite their theoretical benefits in **inflammatory otitis media**.

2. **Lack of Clinical Clarity in Choosing Between Formulations**
   Most prescribers decide based on **site of application** or **severity**, but there is no unified approach. Many respondents reported making choices based on **availability or brand familiarity**, revealing weak concentration-specific positioning.

3. **Neutral Brand Perception vs. Competitors**
   While Cavimus was rated as **equally effective or slightly better** than other Tacrolimus ointments, it did not exhibit standout advantages—suggesting the need for **differentiation via segmentation, education, or patient-centric enhancements**.

4. **Low Awareness Among Patients**
   Only **a third of patients** knew about the difference between Cavimus and Cavimus Forte, and a significant portion were **not satisfied** with results or **unclear about instructions**—which negatively impacts adherence and perception.

5. **Demand for Better Segmentation and Packaging**
   Over **75% of respondents** believed that product usage could be better tailored based on **age, skin type, or indication**. Suggested improvements included **clearer instructions, lower cost**, and more **patient-friendly communication**.

Strategic Implications

- **ENT-Specific Positioning**: A strong opportunity exists to reposition Cavimus Forte as a **safe, non-steroidal anti-inflammatory** for resistant or chronic otitis media cases—backed by clinician training and pilot ENT usage studies.
- **Patient Education Overhaul**: Improved **labeling, usage instructions**, and **digital guidance** (e.g., QR-linked videos) can enhance patient trust and outcomes.
- **Prescriber Differentiation Toolkit**: Develop quick-reference cards or infographics for HCPs to reinforce **when to use 0.03% vs. 0.1%** based on severity, age, and body site.
- **Packaging Innovation**: Consider introducing **ENT-friendly formats** (e.g., applicator tubes or ear-safe droppers) to support otologic applications.

Final Reflection

Resegmentation is not just a marketing shift—it is a clinical necessity when patient profiles, treatment settings, and product options become more diverse. For Tacrolimus ointments like Cavimus and Cavimus Forte, **clarity, communication, and context** will determine their future success in both dermatology and emerging ENT indications like otitis media.

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