Summary Report

Tranilast

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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REVIEW OF NOMINATIONS

Tranilast (UNII code: HVF50SMY6E) was nominated for inclusion on the 503B Bulks List by the Outsourcing Facilities Association (OFA) and Sincerus Florida, LLC. While the exact medical condition for which the compounded product is being requested is generally unknown, tranilast is generally used to treat pruritus. Tranilast will be compounded as various topical dosage forms and strengths based on the prescriber's request; the therapeutic dose ranges from 0.5-1%. Additionally, tranilast will be compounded as a 0.5-1% topical cream, gel, and ointment for treatment of pruritus.

Tranilast was nominated for use in combination with additional active pharmaceutical ingredients (API), refer to Table 7 for the nominated combination formulations.

Reasons provided for nomination to 503B Bulks List include:

- Patients respond differently to drug products and the compounded product may be the only formulation to effectively treat the indication it is intended to treat.
- There are no FDA-approved drugs containing tranilast.
- Compounding from bulk ensures that only the ingredients necessary to achieve the desired clinical outcome are utilized, eliminating any possible irritating, hazardous, or allergenic ingredients.
- Commercially available finished products have an inherent variance in potency which has the potential to introduce unacceptable inaccuracies into the compounded product.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of tranilast products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for tranilast; name variations of tranilast were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient; strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing tranilast. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through January 24, 2019. The search included a combination of (tranilast[TIAB] OR "N-(3,4-Dimethoxycinnamoyl) anthranilic acid"[TIAB] OR rizaben[TIAB]) AND (treatment[TIAB] OR therapy[TIAB] OR therapeutic*[TIAB] OR clinical[TIAB] OR topical[TIAB] OR skin[TIAB] OR derm*[TIAB]) AND (humans[MeSH Terms] AND English[lang]) NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Additional exclusion criteria include any dosage form/ROA that differed from the nominated dosage form/ROA. Articles were considered relevant based on the identification of a clinical use of tranilast or the implementation of tranilast in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

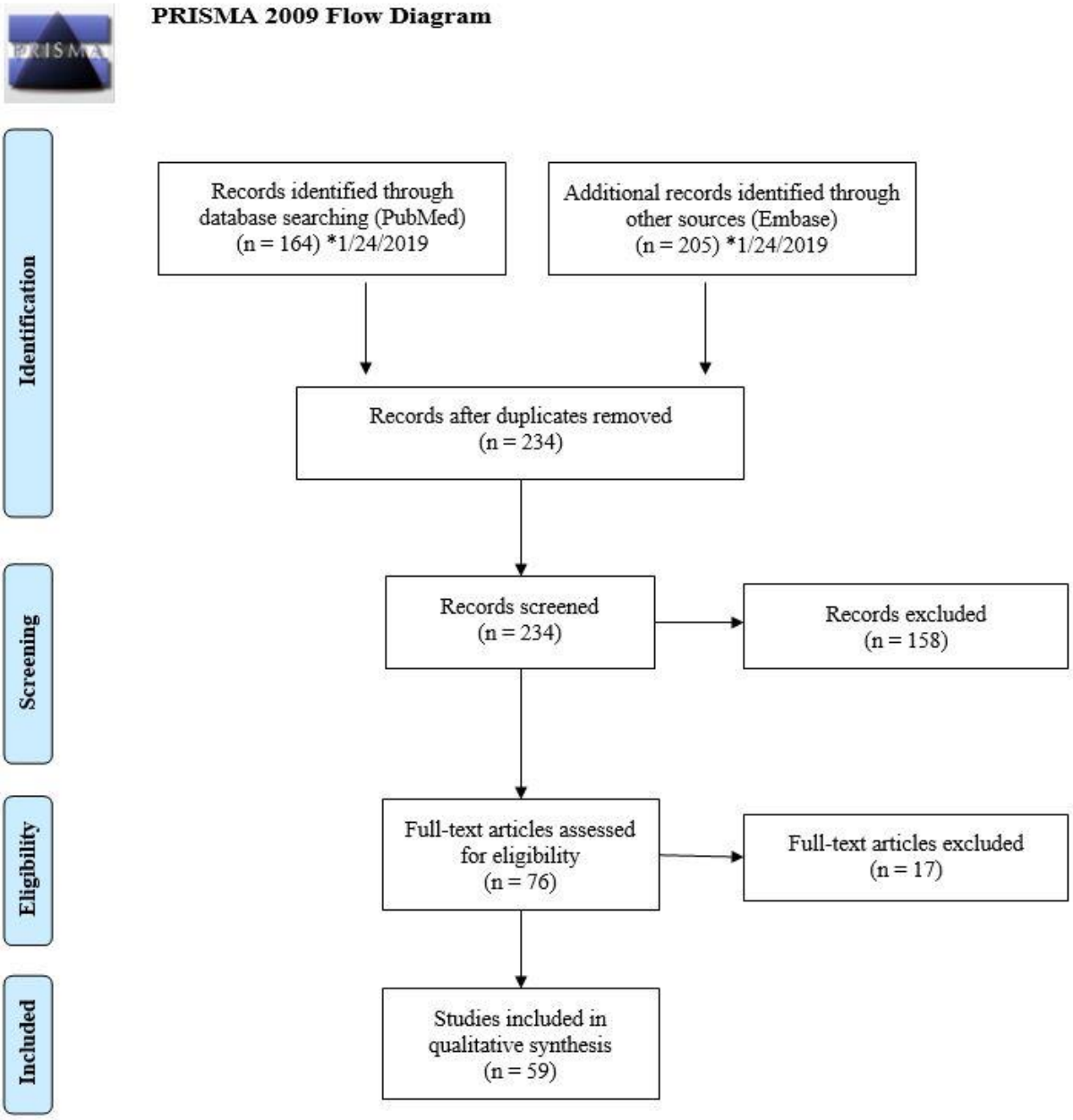
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for tranilast use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of tranilast compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indications from the nominations and the results of the literature review, six (6) medical specialties that would potentially use tranilast were identified: allergy and immunology, cardiology, dermatology, naturopathy, rheumatology, and wound care. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. One (1) expert was contacted for an interview, of which one (1) accepted and zero (0) declined interviews. The interview was recorded and transcribed via ©Rev.com. QSR International's NVivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for allergy and immunology, cardiology, dermatology, naturopathy, rheumatology, and wound care, identified from the nominations, literature review, and interviews, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

Ane online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to 10 associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Allergy/Immunology	American Academy of Allergy, Asthma and Immunology (AAAI)
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)
Naturopathy	American Association of Naturopathic Physicians (AANP)
Rheumatology	American College of Rheumatology (ACR)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Allergy/Immunology	American College of Allergy, Asthma & Immunology (ACAAI)	Declined, "unaware of any bulk drug substances used by allergies in their practices *[sic]*"
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Wound Care	American Professional Wound Care Association (APWCA)	Failed to respond
	Wound Healing Society (WHS)	Failed to respond

CURRENT AND HISTORIC USE

Summary of background information

- Tranilast is not available as an FDA-approved product.
- Tranilast is not available as an OTC product in the US.
- There is no current United States Pharmacopeia (USP) monograph for tranilast.
- Tranilast is not available in any of the selected non-US countries and regions. However, the EU has granted tranilast orphan designation for the prevention of scarring post glaucoma filtration surgery.

Table 3. Currently approved products – US

No approved products in the US

Table 4. Currently approved products – select non-US countries and regions

No approved products in the selected non-US countries and regions

Summary of literature review

- Total number of studies included: 59 (35 descriptive and 24 experimental studies).
- Most of the studies were from Japan (47).
- The indications for the use of tranilast in the US included prevention of restenosis, hives, hyperuricemia, seasonal nasal congestion, and wounds and scars. The most common indications from the non-US studies were wounds and scars and the prevention of restenosis.
- While combination products were identified, none reflected the ones provided by the nominators.
- Compounded products were identified from the US studies.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1-35]	35
Experimental[36-59]	24
Observational	0

Table 6. Number of studies by country

Country	Number of Studies
Australia[47]	1
Brazil[36]	1
China[25]	1
Iran[2]	1
Israel[44]	1
Japan[3-10,12-21,26-30,32-35,37-40,42,43,45,46,48-59]	47
South Korea[11]	1
US[23,24,31,41]	4
Multiple Countries • US, Portugal[1] • Israel, UK[22]	2
	Total US[a]: 5 Total non-US Countries[a]: 55

[a]Study 1 counted in both US and non-US total.

Table 7. Number of studies by combinations

	Combination Formula	Number of Studies
Nominated	Tranilast 1% / Aloe Vera 0.2% / Lidocaine 2% / Mupirocin 2%	0
	Tranilast 1% / Aloe Vera 0.2% / Metronidazole 1% / Mupirocin 2%	0
	Tranilast 0.5% / Betamethasone dipropionate 0.05% / Menthol 2% / Pramoxine hydrochloride 1%	0
	Tranilast 0.5% / Desoximetasone 0.05% / Menthol 2% / Pramoxine hydrochloride 1%	0
	Tranilast 1% / Levocetirizine dihydrochloride 2% / Mupirocin 2% / Triamcinolone acetonide 0.025%	0
	Tranilast 1% / Pentoxifylline 0.5% / Triamcinolone acetonide 0.1% / Zinc oxide 5%	0
	Tranilast 0.5% / Hydrocortisone 2.5% / Levocetirizine dihydrochloride 2%	0
	Tranilast 1% / Metronidazole 1% / Mupirocin 2%	0
	Tranilast 1% / Niacinamide 4% / Triamcinolone acetonide 0.1%	0
	Tranilast 1% / Pentoxifylline 0.5% / Triamcinolone acetonide 0.1%	0
Others found in literature	Tranilast 1% / Caffeine 1% / Pentoxifylline 1% – topical[1]	1
	Tranilast 1% / Betamethasone valerate 0.1% – topical[47]	1

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Prevention of restenosis[23,41]	600-900mg/day	–	–	–	1-3 months
Hives[31]	Apply 2x/day	10%	Cream	Topical	9 days
Hyperuricemia[24]	100-900mg/day	–	–	–	4 weeks
Seasonal nasal congestion[31]	Apply 2x/day	10%	Cream	Topical	2 weeks
Surgical/trauma/burn wounds and scars[1]	Apply 2x/day	1%	–	Topical	3 weeks

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Surgical/trauma/burn wounds and scars[1,2,8,22,44,46,52]	5mg/kg/day	–	Powdered	Oral	3 months
	Apply 2x/day	1-8%	Liposomal gel	Topical	3 weeks-3 months
	12mg	12mg/1.5mL	Solution	Transdermal	At least 8 treatments
	300mg/day	–	–	–	18 weeks
Prevention of restenosis[2,19,20,45,56,57]	300-600mg/day	–	Capsule	Oral	3 months
Azoospermia[34], oligozoospermia[38,59], oligoasthenozoospermia[39]	300mg/day	–	Tablet	Oral	12 weeks-1 year
Annular elastocytic giant cell granuloma[2,11,16]	5mg/kg/day	–	–	Oral	3 months
	300mg/day	–	–	–	–

Diabetic nephropathy[2,54,55]	100-300mg/day	–	–	–	–
Prevention of pterygium recurrence after surgery[2,30,36]	0.1mL	0.5%	Solution	Subconjunctival injection	Once
	–	–	Solution	Topical	At least 1 month
Scleroderma[27,47] with pseudoainhum[26]	200mg/day	–	–	Oral	–
	–	1%	–	Topical	3 months
	300mg/day	–	–	–	–
Solitary mastocytoma[2,7,22]	5mg/kg/day	–	–	Oral	4 months-2.5 years
Castration resistant prostate cancer[22,43]	300mg/day	–	–	Oral	2-25 months
Cutaneous sarcoidosis[2,33]	300mg/day	–	–	–	3-6 months
Desmoid tumor[2,22]	300-900mg/day	–	–	Oral	–
Dry eye associated with chronic graft-versus-host disease[2,49]	Apply 4x/day	–	Eye drops	Topical	3 months
Intraocular pressure and bleb formation after glaucoma filtering surgery[2,37]	Apply 4x/day	0.5%	Eye drops	Topical	3 months
Lupus miliaris disseminates faciei[2,9]	300mg/day	–	–	Oral	2-5 months
Muscular dystrophy with cardiomyopathy[12,13]	150-300mg/day	–	–	–	At least 3 months
Otitis media[40,50]	0.5mg/kg/day	–	–	Oral	At least 1 month
	0.05mg/kg/day	–	–	–	6 weeks
Seasonal nasal congestion[51,58]	300mg/day	100mg/capsule	Capsule	Oral	4-11 weeks

Vulval syringoma[2,22]	300mg/day	–	–	–	6 months
Bilateral corneal keloid[3]	–	–	Eye drops	Topical	–
Bronchial asthma[53]	5-10mg/kg/day	–	–	Oral	4 weeks
Cheilitis granulomatosa[6]	240mg/day	–	–	Oral	3 months
Concave deformity following traumatic hematoma[17]	60-150mg/day	–	–	Oral	4 months
	5mg/kg/day	–	–		
Crohn's Disease[2]	600mg/day	–	–	–	–
Disseminated granulomatous skin lesions associated with myelodysplastic syndrome[35]	–	–	–	Oral	At least 3 months
Endometriosis pelvic pain[42]	300mg/day	–	–	–	6 months
Eosinophilic pustular folliculitis[14]	300mg/day	–	–	Oral	4 weeks
Epithelioid hemagioma[21]	300-600mg/day	–	–	–	1.5 years
Generalized lichen nitidus[10]	400mg/day	–	–	Oral	1.5 months
Granuloma annulare[32]	300mg/day	–	–	Oral	At least 3 months
Granulomatous blepharitis[4]	300mg/day	–	–	Oral	7 months
Laryngeal granuloma[48]	300mg/day	–	–	–	48 weeks
Ocular inflammation[2]	–	0.5%	Eye drops	Topical	–
Pemphigus vulgaris[15]	300mg/day	–	–	–	–
Prurigo nodularis[5]	200mg/day	–	–	–	At least 4 months

Scleredema diabeticorum[25]	0.3g/day	–	–	Oral	3 months
Secondary lymphedema[28]	400mg/day	–	–	Oral	1 month
Unilateral Schamberg disease[18]	300mg/day	–	–	Oral	–
Vulvitis granulomatosa[29]	300mg/day	–	–	Oral	8 months

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 10. Compounded products – US

Indication	Publication Year	Compounding Method	Dosage Form	Final Strength
Seasonal nasal congestion[31]	2007	• Tranilast with a solubilizer in a vanishing cream base	Cream	10%
Surgical/trauma/burn wounds and scars[1]	2014	• Tranilast with caffeine, pentoxifylline, and pracaxi oil in an anhydrous silicone base	–	–

Abbreviation: "–", not mentioned.

Table 11. Compounded products – non-US countries

No compounded products from reported studies

Summary of focus groups/interviews of medical experts and specialty organizations

One (1) interview was conducted.

Table 12. Overview of interviewee

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Tranilast	Interview Summary Response
DER_05	MD	Dermatology/Immunology	Independent consultant	No	• No personal experience with tranilast. • No data to support the safety and efficacy .

Abbreviation: MD, Doctor of Medicine.

Use of tranilast

- The interviewee had no personal experience with tranilast "because it's not been easy to get in the US. At the times that I was practicing, we couldn't get it."
    - Interviewee commented that it has been approved in Korea and Japan, and there has been some pre-clinical models looking at mice to see if it would help with hypertrophic scarring and/or keloid formation by decreasing TGF-beta. However, "the big issue with the scar and with the keloids is really whether you're going to be able to deliver the drug deep enough into the skin for it to work."
    - When asked about the use for hives identified in the literature review, the interviewee commented that mast cells "are part of the source for that TGF-beta. So that's why people might be thinking that they would work there."

Tranilast through outsourcing facilities

- The interviewee stated that they have no concern with tranilast not being available, and if somebody wants to file an IND and prove that it is safe and effective, then they can do so. Interviewee did not "have a problem with the products going away. There's no data to support the safety efficacy."

Summary of survey results

Table 13. Characteristics of survey respondents [17 people responded to the survey[a]]

Board Certification	DO	MD	ND	No Response
Allergy and Immunology	0	1	0	0
Cardiovascular Disease	0	0	0	1
Dermatology	0	1	0	0
Fellow of the American Board of Naturopathic Oncology	0	0	1	0
Naturopathic Doctor	0	0	3	0
Naturopathic Physician	0	0	3	0
Rheumatology	1	0	0	0
No Response	0	0	0	9

Abbreviations: DO, Doctor of Osteopathic Medicine; MD, Doctor of Medicine; ND, Naturopathic Doctor.
[a]Some respondents reported more than one (1) board certification.

Table 14. Types of products used, prescribed, or recommended

No survey respondents reported using tranilast

Table 15. Compounded use of tranilast in practice

No survey respondents reported using tranilast

Table 16. Indications for which tranilast is considered a standard therapy

No survey respondents reported using tranilast

Table 17. Reasons for using compounded product instead of the FDA-approved products

No survey respondents reported using tranilast

Table 18. Change in frequency of compounded tranilast usage over the past 5 years

No survey respondents reported using tranilast

Table 19. Do you stock non-patient specific compounded tranilast in your practice?

No survey respondents reported using tranilast

Table 20. Questions related to stocking non-patient specific compounded tranilast

No survey respondents reported using tranilast

CONCLUSION

Tranilast (UNII code: HVF50SMY6E) was nominated for inclusion on the 503B Bulks List for pruritus and other unknown indications via various topical dosage forms. Tranilast is not approved in any of the national medical registries searched, but the EU has granted it orphan designation for the prevention of scarring post glaucoma filtration surgery.

From the literature review conducted, tranilast was used for a variety of indications in the US studies, including prevention of restenosis, hives, hyperuricemia, seasonal nasal congestion, and wounds and scars. In the non-US studies, the most common indications were wounds and scars and the prevention of restenosis. Compounded products were identified from the US studies, but not for the nominated indications.

The interviewee had no personal experience with tranilast due to it being unavailable when they were in practice. The interviewee commented about the potential for using it for hypertrophic scarring and/or keloid formation but stated that since there is no data supporting its safety and efficacy, does not anticipate issues if tranilast became unavailable.

From the survey responses, none of the 17 respondents reported using, prescribing, or recommending tranilast.

APPENDICES

Appendix 1. References

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Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **tranilast**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Tranilast

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **tranilast**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for tranilast? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for tranilast? Please check all th... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for tranilast? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **tranilast** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3. Do you use compounded **tranilast** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded tranilast as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded tranilast as a single agent active ingredient, or as one active ingredient... = Combination

Q4. In which combination(s) do you use compounded **tranilast**? Please check all that apply.

- ☐ Tranilast 0.5% / Hydrocortisone 2.5% / Levocetirizine dihydrochloride 2%
- ☐ Tranilast 0.5% / Betamethasone dipropionate 0.05% / Menthol 2% / Pramoxine 1%
- ☐ Tranilast 0.5% / Desoximetasone 0.05% / Menthol 2% / Pramoxine HCl 1%
- ☐ Tranilast 1% / Metronidazole 1% / Mupirocin 2%
- ☐ Tranilast 1% / Aloe vera 0.2% / Metronidazole 1% / Mupirocin 2%
- ☐ Tranilast 1% / Aloe vera 0.2% / Lidocaine 2% / Mupirocin 2%
- ☐ Tranilast 1% / Niacinamide 4% / Triamcinolone acetonide 0.1%
- ☐ Tranilast 1% / Pentoxifylline 0.5% / Triamcinolone acetonide 0.1%
- ☐ Tranilast 1% / Pentoxifylline 0.5% / Triamcinolone acetonide 0.1% / Zinc oxide 5%
- ☐ Tranilast 1% / Levocetirizine dihydrochloride 2% / Mupirocin 2% / Triamcinolone acetonide 0.025%
- ☐ Other (please describe) _____

Q5. For which, if any, diseases or conditions do you consider compounded **tranilast** standard therapy?

_____

Q6. Does your specialty describe the use of compounded **tranilast** in medical practice guidelines or other resources?

_____

Q7. Over the past 5 years, has the frequency in which you have used compounded **tranilast** changed?

- Yes - I use it **MORE** often now (briefly describe why) _____
- Yes - I use it **LESS** often now (briefly describe why) _____
- No - use has remained consistent

Q8. Why do you use compounded **tranilast** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **tranilast** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded tranilast in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded tranilast in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **tranilast**? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **tranilast**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **tranilast**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded tranilast? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded tranilast? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded tranilast? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **tranilast** standard therapy?

_____

Q14. Does your specialty describe the use of **tranilast** in medical practice guidelines or other resources?

_____

End of Block: Tranilast

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- ▢ Doctor of Medicine (MD)
- ▢ Doctor of Osteopathic Medicine (DO)
- ▢ Doctor of Medicine in Dentistry (DMD/DDS)
- ▢ Naturopathic Doctor (ND)
- ▢ Nurse Practitioner (NP)
- ▢ Physician Assistant (PA)
- ▢ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ▢ No Board certification
- ▢ Allergy and Immunology
- ▢ Anesthesiology
- ▢ Cardiovascular Disease
- ▢ Critical Care Medicine
- ▢ Dermatology
- ▢ Emergency Medicine
- ▢ Endocrinology, Diabetes and Metabolism
- ▢ Family Medicine
- ▢ Gastroenterology
- ▢ Hematology
- ▢ Infectious Disease
- ▢ Internal Medicine
- ▢ Medical Toxicology
- ▢ Naturopathic Doctor
- ▢ Naturopathic Physician
- ▢ Nephrology
- ▢ Neurology
- ▢ Obstetrics and Gynecology
- ▢ Oncology
- ▢ Ophthalmology
- ▢ Otolaryngology
- ▢ Pain Medicine
- ▢ Pediatrics
- ▢ Psychiatry
- ▢ Rheumatology

- ☐ Sleep Medicine
- ☐ Surgery (please describe) _____
- ☐ Urology
- ☐ Other (please describe) _____

End of Block: Background Information