

Summary Report

Zinc Pyrithione

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 NOMINATION

Zinc pyrithione (UNII: R953O2RHZ5) was nominated for inclusion on the 503B Bulks List by the Outsourcing Facility Association (OFA) and Sincerus Florida, LLC. The exact medical condition for which the compounded product is being requested is generally unknown, however zinc pyrithione is commonly used to treat dermatitis and seborrheic dermatitis. Zinc pyrithione was nominated to be compounded as various topical dosage forms and strengths requested by the prescriber, the therapeutic dose range is 0.2%-1%. Sincerus identified the need to compound zinc pyrithione in combination with other active pharmaceutical ingredients (API) for a synergistic effect in treating dermatitis, however the additional API were not specified. OFA stated that zinc pyrithione has been used to compound products with multiple API, refer to Table 7 for the combination products included.

The reasons provided for nomination to the 503B Bulks List include:

- Patients respond differently to drug products and the compounded product may be the only formulation effective to treat the desired indication.
- Compounding from a bulk drug substance means that only the ingredients necessary to achieve the desired clinical outcome are utilized eliminating any fillers, excipients, binders, dyes, preservatives, or other materials that may be irritating, hazardous, or allergenic.
- Variance in the API of finished products may introduce unacceptable inaccuracies into the compounded product; compounding from the bulk substance is more accurate.
- Excipients found in the over-the-counter (OTC) products are not desired in the compounded formulations.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of zinc pyrithione 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 zinc pyrithione; name variations of zinc pyrithione 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

zinc pyrithione. 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 February 2, 2019. The search included a combination of (“zinc pyrithione”[TIAB] OR “zinc pyridinethione”[TIAB] OR zincon[TIAB] OR znp[TIAB] OR zpt[TIAB] AND (treatment[TIAB] OR therapy[TIAB] OR therapeutic*[TIAB] OR topical[TIAB] OR clinical[TIAB] OR psoriasis[TIAB] OR dandruff[TIAB] OR skin[TIAB] OR dermat*[TIAB] OR hair[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. Articles were considered relevant based on the identification of a clinical use of zinc pyrithione or the implementation of zinc pyrithione 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.

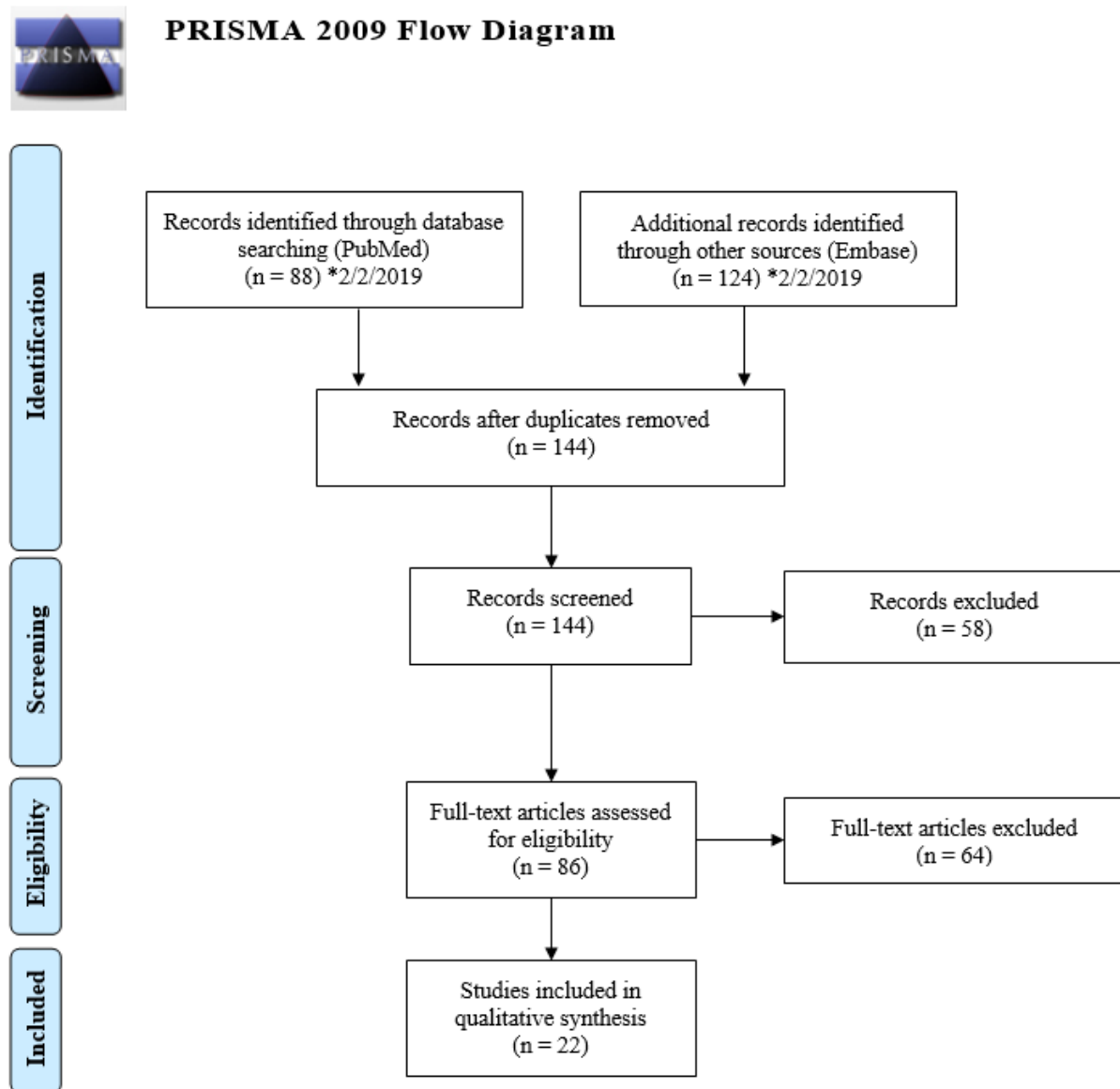
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for zinc pyrithione 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 zinc pyrithione 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). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: 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, one (1) medical specialty that would potentially use zinc pyrithione was identified: dermatology. Semi-structured interviews were conducted with subject matter experts within this specialty. 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 interviews, of which one (1) accepted and zero declined interviews. Interviews were 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 dermatology, identified from the nominations, literature review, and interview, 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.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to two (2) 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
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond

CURRENT AND HISTORIC USE

Summary of background information

Zinc pyrithione is not available as an FDA-approved product. There was an FDA-approved 0.3% topical lotion marketed as Head and Shoulders; however, this product has been discontinued. Zinc pyrithione is available OTC in the US in various topical dosage forms. Zinc pyrithione does not have a United States Pharmacopeia (USP) monograph.

Zinc pyrithione is available as an OTC product in various topical dosage forms in Canada, New Zealand, and Hong Kong. Zinc pyrithione is available as an approved product in Abu Dhabi.

Table 3. Currently approved products – US

No approved products in the US

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

Product	Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
					Country	Status	Approval Date
Desquamant	Pyrrithione zinc	15mg/g	Cream	–	Abu Dhabi	Active	–

Abbreviations: “–”, not mentioned; ROA, route of administration

^aMedicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, route of administration and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or routes of administration similar to those requested in the nominations. See Methodology for full explanation.

Summary of literature review

The most common indication for both the US and non-US studies was dandruff/seborrheic dermatitis. All of the studies utilized a topical dosage form and concentrations ranged from 0.25% -2%. No compounded products from the US were identified and no studies used zinc pyrithione in the nominated combinations.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive	0
Experimental ¹⁻²²	22
Observational	0

Table 6. Number of studies by country

Country	Number of Studies
Belgium ^{3,4,22}	3
Canada ¹⁵	1
China ⁹	1
Denmark ¹⁴	1
France ²⁰	1
India ^{7,8}	2
Iran ⁶	1
Korea ¹¹	1
Sweden ¹⁹	1
UK ^{1,2,5,21}	4
US ^{13,16}	2
Multiple Countries	
• Canada and US ^{10,17,18}	3
• France and Portugal ¹²	1
Total US: 5	
Total non-US Countries: 17	

Table 7. Number of studies by combinations

	Combination Formula	Number of Studies
Nominated	Zinc pyrithione 0.2% / clobetasol propionate 0.05% / nia cinamide 4%	0
	Zinc pyrithione 1% / ciclopirox 0.77% / salicylic acid 2%	0
	Zinc pyrithione 1% / clobetasol propionate 0.05% / levocetirizine dihydrochloride 2%	0
	Zinc pyrithione 1% / desoximetasone 0.05% / nia cinamide 4%	0
	Zinc pyrithione 1% / ketoconazole 2% / salicylic acid 2%	0
	Zinc pyrithione 1% / ciclopirox 0.77% / clobetasol propionate 0.05% / salicylic acid 3%	0
	Zinc pyrithione 1% / ciclopirox 0.77% / clobetasol propionate 0.05% / tea tree oil 1%	0
	Zinc pyrithione 1% / ciclopirox 0.77% / salicylic acid 2% / tea tree oil 1%	0
	Zinc pyrithione 1% / clobetasol propionate 0.05% / levocetirizine dihydrochloride 2% / tea tree oil 1%	0
	Zinc pyrithione 1% / ciclopirox 0.77% / clobetasol propionate 0.05% / salicylic acid 3% / tea tree oil 1%	0
Others found in literature	Zinc pyrithione 1% / ciclopirox olamine 1.5% shampoo ²⁰	1
	Zinc pyrithione 1% / polytar 1% shampoo ⁸	1
	Zinc pyrithione / beta-glycyrrhetic acid / cyclopiroxolamine shampoo ¹²	1

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Dandruff/seborrheic dermatitis ^{13,17,18}	Apply 2-3x/week	1%	Shampoo	Topical	3-6 weeks
Psoriasis ¹⁶	Apply 2x/day	0.25%	Spray	Topical	2 weeks
Scalp health ¹⁰	Apply 3x/week	1%	Shampoo	Topical	16 weeks

Abbreviation: ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Dandruff/seborrheic dermatitis ^{1-3,5,7-9,11,12,14,15,19-22}	Apply 1-4x/week	0.5%-2%	Shampoo	Topical	3-10 weeks
Psoriasis ⁶	Apply 2x/day	0.25%	Cream	Topical	3 months
Hair shedding ⁴	Apply 2-3x/week	1%	Shampoo	Topical	6 months

Abbreviation: ROA, route of administration.

Table 10. Compounded products – US

No compounded products from reported studies

Table 11. Compounded products – non-US countries

Indication	Compounding Method	Dosage Form	Final Strength
Psoriasis ⁶	<ul style="list-style-type: none"> • Zinc pyrithione 0.25% <ul style="list-style-type: none"> ○ Emollient base (olive oil 8%, sorbitan isostearate 1%, propylene glycol 5%, water up to 100%) 	Cream	0.25%

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 Zinc Pyrithione	Interview Summary Response
DER_05	MD	Dermatology Dermatology/Immunology	Consultant	Yes	<ul style="list-style-type: none"> • Is found in Head and Shoulders • Some people use for subdermal psoriasis or any type of sclerosis disorder to decrease inflammation

Abbreviations: MD, Doctor of Medicine

- Clinical use of zinc pyrithione
 - Interviewee stated that zinc pyrithione is found in Head and Shoulders and is a well-known anti-dandruff shampoo
 - Can be used for subdermal psoriasis or any type of sclerosis disorder to decrease inflammation
 - Interviewee stated it might fall in “that OTC place where there hasn’t been a regular trial conducted to prove that it actually works, we all assume it works, because we’ve been using it for 50 years.”
- Administration
 - Classically a wash-off product mostly in shampoos, not generally a leave-on product. Was not familiar with the use as a topical spray, is more familiar with removal after application, stated “as long as it’s in a concentration that’s not so high that it’s going to be irritating to the skin, I suppose you can do that, I worry about whether it would be irritating.”
 - When asked about the combination products identified in the nomination, the interviewee stated that a lot of the combinations included keratolytics, however the interviewee did not discuss whether this would be clinically necessary
- Need for compounded zinc pyrithione
 - Interviewee does not know the rationale behind compounding “unless if somebody is going to be dispensing it in their office in some form, it just doesn’t make a lot of sense.”
 - There are several OTC pyrithione containing products on the market
 - Dermatologists do like to “mix our favorite recipes up with a little bit of this and a little of that, but, again, you could still write a prescription for someone to go get that product compounded.”
 - Interviewee stated that it does not make sense for this to be administered in-office

Summary of survey results

Table 13. Characteristics of survey respondents (3 people responded to the survey)

Board Certification	MD
Dermatology	3

Abbreviation: MD, Doctor of Medicine.

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

Types of Products	Respondents, n (N=2)
Compounded	0
FDA-approved	0
Over-the-counter	2
Dietary	0
Unsure	0

Table 15. Compounded use of zinc pyrithione in practice

No respondents stated use of compounded zinc pyrithione

Table 16. Indications for which zinc pyrithione is considered a standard therapy

Indication	Standard Therapy	
	Compounded, n (N=0)	Non-compounded, n (N=2)
Seborrheic dermatitis	0	2

Table 17. Reasons for using a compounded product instead of an FDA-approved product

No respondents stated use of compounded zinc pyrithione

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

No respondents stated use of compounded zinc pyrithione

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

No respondents stated use of compounded zinc pyrithione

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

No respondents stated use of compounded zinc pyrithione

CONCLUSION

Zinc pyrithione (UNII: R953O2RHZ5) was nominated for inclusion on the 503B Bulks List and while the exact medical condition for which the compounded product is being requested is generally unknown, zinc pyrithione is commonly used to treat dermatitis and seborrheic dermatitis. The desired compounded products include various topical dosage forms and strengths requested by the prescriber, the therapeutic dose range is 0.2% -1%.

Zinc pyrithione is not available as an FDA-approved product however, there are various topical dosage forms available OTC in the US. Zinc pyrithione does not have a United States Pharmacopeia (USP) monograph.

From the literature review, the most common indication for both the US and non-US studies was dandruff/seborrheic dermatitis. All of the studies utilized a topical dosage form and concentrations ranged from 0.25% -2%. No compounded products from the US were identified and no studies were identified that used zinc pyrithione in the combinations included in the nomination.

From the interview, zinc pyrithione is generally used as a shampoo to treat dandruff, subdermal psoriasis, or any type of sclerosis disorder to decrease inflammation. Due to the availability of OTC products, the interviewee does not know the rationale behind compounding and does not think it makes sense for this to be administered in-office.

From the survey, two (2) of the three (3) respondents reported using zinc pyrithione, however they all utilized OTC products. The respondents did state that zinc pyrithione is the standard of care for seborrheic dermatitis.

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 **zinc pyrithione**. 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: Zinc pyrithione

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **zinc pyrithione**? 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 zinc pyrithione? Please check...
!= Compounded drug product*

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

Display This Question:

*If What type(s) of product(s) do you use, prescribe, or recommend for zinc pyrithione? Please check... =
Compounded drug product*

Q2. Please list any conditions or diseases for which you use compounded **zinc pyrithione** 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 **zinc pyrithione** 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 zinc pyrithione as a single agent active ingredient, or as one active ingre...
!= Combination*

Display This Question:

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

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

- Zinc pyrithione 0.2% / Clobetasol propionate 0.05% / Niacinamide 4%
- Zinc pyrithione 1% / Ciclopirox 0.77% / Salicylic acid 2%
- Zinc pyrithione 1% / Ciclopirox 0.77% / Clobetasol propionate 0.05% / Salicylic acid 2%
- Zinc pyrithione 1% / Ciclopirox 0.77% / Clobetasol propionate 0.05% / Tea tree oil 1%
- Zinc pyrithione 1% / Ciclopirox 0.77% / Salicylic acid 2% / Tea tree oil 1%
- Zinc pyrithione 1% / Ciclopirox 0.77% / Clobetasol propionate 0.05% / Salicylic acid 3% / Tea tree oil 1%
- Zinc pyrithione 1% / Clobetasol propionate 0.05% / Levocetirizine dihydrochloride 2%
- Zinc pyrithione 1% / Clobetasol propionate 0.05% / Levocetirizine dihydrochloride 2% / Tea tree oil 1%
- Zinc pyrithione 1% / Desoximetasone 0.05% / Niacinamide 4%
- Zinc pyrithione 1% / Ketoconazole 2% / Salicylic acid 2%
- Other (please describe) _____

Page Break

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

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

Q7. Over the past 5 years, has the frequency in which you have used compounded **zinc pyrithione** 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 **zinc pyrithione** instead of any FDA-approved drug product?

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

Yes

No

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

Page Break

Display This Question:

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

Q10. In what practice location(s) do you stock non-patient-specific compounded **zinc pyrithione**? 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 **zinc pyrithione**? 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 **zinc pyrithione**? 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 zinc pyrithione? Please check all that... = Convenience

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

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

Page Break _____

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

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

End of Block: Zinc pyrithione

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