Clinical Study Protocol

AnOpen-Label,ObservationalStudyEvaluatingTopicort®TopicalSpray0.25%(desoximetasone)inPatientswith ScalpPsoriasis

Testing Facility

PsoriasisTreatmentCenterofCentralNewJersey

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PROTOCOL SYNOPSIS:

Study Title	AnOpen -Label,ObservationalStudyEvaluating Topicort®TopicalSpray0.25% (desoximetasone)inPatientswithScalpPsoriasis
Sponsors	JerryBagel,MD
Study Objectives	**Primary Objective:** To exploretheefficacyofTopicort®TopicalSprayatweeks4 and16 withrespectto Investigator GlobalAssessme nt(scalponly), Psoriasis ScalpSeverityIndex(PSSI) , andScalpSurfaceArea(SSA) **Secondary Objectives:** PGAxBSA,patient reportedoutcomes ,adverseevents
Study Design	A single center,observationalstudyof2 0subjectstoassess4weeksof therapy with Topicort® BIDand12weeks BIDontwoconsecutivedaysaweek patients with scalppsoriasis
Study Centers	PsoriasisTreatmentCenterofCentralNewJersey
Study Population	Adultmaleandfemalesubjectswithmoderatetoseverechronicplaque psoriasis
Main Inclusion Criteria	Subjectsmustmeetthefollowingcriteriatobeenrolledinthisstudy: 1. Maleorfemaleadult ≥ 18yearsofage; 2. Chronicscalppsoriasis ≥ 30% 3. Investigator GlobalAssessment(scalponly) ofmildorgreater
Main Exclusion Criteria	Subjectswhomeetanyofthefollowingcriteriawillbeexcludedfrom participationinthisstudy: 1. Subjectswithnonplaquetypepsoriasis(e.g.guttate and erythrodermic). 2. Subjectswith<30%scalppsoriasis. 3. Useofprohibitedmedications duringstudyperiod.
Study Drug Dosage and Administration	Allpati entswillreceiveTopicort ® BIDfor4weeks. Afterweek4pat ientswillreceiveTopicort willreceiveTopicort® BIDontwo consecutivedaysaweek for12weeks . Patientswilltreatotherbodyareas affectedbyplaquepsoriasiswithTopicort®duringthestudyperiod(excludes face,groin,axilla)
Study Endpoints	Improvementafter 4and 16weeksof: InvestigatorGlobalAssessment(scalponly) PsoriasisScalpSeverityIndex Scalpsurfacearea Physician Global Assessment x Body Surface Area Pain,itching,scaling(scalponly) Scalpdex
Study Duration	***16 weeks***

2 ETHICS AND REGULATORY OBLIGATIONS

2.1 Institutional Review Board (IRB)

Written IRB approval of this protocol must be obtained before the study is initiated. Compliance with Title 21 of the US Code of Federal Regulations (CFR), Part 56, is required in order to protect the rights and welfare of human subjects involved in this study.

2.2 Ethical Conduct of the Study

The study will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and its amendments. In addition, the study will be performed in compliance with Good Clinical Practices (GCP), including the archiving of essential documents.

2.3 Subject Information and Consent

The Informed Consent Form will be reviewed and approved by the IRB. The purpose, duration and possible risks and benefits will be explained to each potential subject. Consent in writing must be obtained from the subject before enrollment into the study. Consents will be signed and dated as required by Title 21 of CFR, Part 50. The consent will also comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). The original, signed Informed Consent Form will be retained by the Investigator. A signed copy of the Informed Consent Form will be given to the subject. Each subject will be assigned a subject number that will be used in lieu of the subject's name on further research documentation.

3 INTRODUCTION

3.1 Overview of Psoriasis

Psoriasis is a chronic immunological disease characterized by infiltration of the skin with activated T cells and by abnormal keratinocyte proliferation and differentiation, resulting in marked inflammation and thickening of the epidermis. Psoriasis affects 1-3% of the world population, making it one of the most prevalent inflammatory immunological diseases.[1] There are several clinical subtypes of psoriasis: plaque, guttate, erythrodermic, inverse, and pustular. Plaque psoriasis is the most common type of psoriasis affecting 75-80% of psoriasis sufferers.[2] It presents as raised silvery scale, which can cover large areas, with underlying erythema, itching, and discomfort.

3.2 Rationale for Treating Scalp Psoriasis with Corticosteroid Topical Therapy

Scalp psoriasis can have a significant psychosocial impact on a patient's quality of life and the use of topical therapy has shown an increase in quality of life outcomes.[3] Topical steroids play an in important role in the long term management of psoriasis. Data from a study analyzing disease severity and patient treatment satisfaction revealed that patients with psoriasis are often dissatisfied with available treatments.[4] Patient preferences of topical treatments can greatly impact compliance rates. Recent evidence shows that spray is a patient preferred vehicle more than 2 to 1 over creams, ointments, lotions, gel and foams.[5] This study will analyze improvement in scalp psoriasis and patient outcomes.

4. STUDY OBJECTIVE

To explore the effectiveness and safety of Topicort® Topical Spray for patients with scalp plaque psoriasis.

5. INVESTIGATIONAL PLAN

5.1 Overall Study Design and Plan

20 subjects with at least mild scalp psoriasis and scalp surface area greater than or equal to 30%, will receive Topicort® twice daily for 4 weeks followed by twice daily two times a week for 12 weeks.

5.2 Study Population Criteria

Males and females ≥ 18 years of age with plaque type scalp psoriasis

5.2.1 Inclusion Criteria

Patients who meet all of the following criteria will be enrolled in the study:

1. Male or female adults ≥ 18 years of age.
2. Diagnosis of chronic plaque-type scalp psoriasis.
3. IGA of mild or greater (scalp only) determined at screening
4. Scalp surface area of 30% or greater determined at screening
5. Able to give written informed consent prior to performance of any study related procedures.
6. Females of childbearing potential (FCBP) must have a negative pregnancy test at Screening and Baseline. FCBP who engage in activity in which conception is possible must use one of the approved contraceptive options: hormonal contraception; intrauterine device (IUD); tubal ligation; or partner's vasectomy; Male or female condom, diaphragm with spermicide, cervical cap with spermicide, or contraceptive sponge with spermicide.
7. Subject must be in general good health (except for psoriasis) as judged by the Investigator, based on medical history, physical examination.

5.2.2 Exclusion Criteria

Patients will NOT be enrolled in this study if they meet any of the following criteria:

1. <30% scalp surface area
2. Scalp IGA clear or almost clear at time of screening
3. Any condition, which would place the subject at unacceptable risk if he/she were to participate in the study.
4. Pregnant or breast feeding, or considering becoming pregnant during the study.
5. Use of any investigational drug within 4 weeks prior to randomization, or within 5 pharmacokinetic/pharmacodynamic half lives, if known (whichever is longer).
6. Use of oral systemic medications for the treatment of psoriasis within 4 weeks (includes, but not limited to, oral corticosteroids, methotrexate, acitretin, apremilast and cyclosporine).
7. Use of ustekinumab and/or anti-IL-17 biologic therapy within 24 weeks or other experimental or commercially available biologic immune modulator(s) within 12 weeks prior to the first IP dose.
8. Patient used other topical therapies to treat within 2 weeks of the Baseline Visit (not including permitted topical therapy for face, groin and axilla).
9. Patient received UVB phototherapy within 2 weeks of Baseline.
10. Patient received PUVA phototherapy within 4 weeks of Baseline.
11. Patient has a known hypersensitivity to the excipients of Topicort Spray® as stated in the label.

5.3 Source of Subjects and Recruitment Methods

The Investigator will manage the recruitment of subjects upon approval of the study by the Institutional Review Board. Subjects may be recruited from internal patient lists and outside IRB approved advertisements.

5.4 Subject Enrollment and Treatment Assignment

20 subjects of either gender scalp plaque psoriasis will be enrolled to receive open-label Topicort® BID for 4 weeks followed by twice daily two days a week for 12 weeks.

5.5 STUDY TREATMENT

5.5.1 Topicort® Topical Spray 0.25% (desoximetasone)

5.5.1.1 Topicort ® Description

Topicort ® Topical Spray is a Class I, super-potent corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years or older. Each gram of Topicort® Topical Spray 0.25% contains 2.5mg of desoximetasone in a clear, colorless liquid.

5.5.1.2 Topicort® Dosing Schedule

Topicort® will be supplied by Taro Pharmaceuticals U.S.A. Inc. and applied approximately 12 hours apart twice daily for 4 weeks followed by twice daily two times a week - on consecutive days - for 12 weeks (e.g. Saturday, Sunday). Patients will treat other body areas affected by plaque psoriasis with Topicort® during the study period (excludes face, groin, axilla).

5.5.1.3 Topicort® Dispensing and Dosing Record

Subjects will return all unused Topicort® to the study site. Site personnel will keep a record of Topicort® dispensed to and returned by each subject and note any missed doses.

5.5.1.4 Topicort Spray® Dosage Adjustments

If an SAE or an adverse event that is thought to be related to Topicort® and is not alleviated by symptomatic intervention, Topicort® will be discontinued. Subjects who permanently discontinue Topicort® therapy under this protocol should receive standard care of psoriasis treatment as prescribed by their physician.

5.5.2 Permitted Concomitant Therapy

Subjects may use non-steroidal topical medications to face, groin and axilla. Patients may apply Topicort Spray® on arms, legs and trunk to treat body psoriasis. Appropriate interventions (e.g., prescribed medications) may be performed as the investigator deems necessary to treat concomitant illnesses and/or safeguard the subjects' wellbeing. No investigational product or device may be used during the study.

5.6 Study Procedures

5.6.1 Informed Consent

This Study will be conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed consent will be obtained from each subject in writing before participation in the Study. A signed copy of the Informed Consent Form will be provided to each subject. A provision to obtain a signed authorization to provide protected health information to

the study sponsor, internal quality assurance agencies, health insurance agencies, and other parties as specified in the Federal Health Insurance Portability and Accountability Act (HIPAA) privacy regulation will be included in the Informed Consent Document. HIPAA authorization is voluntary. However, since the use and release of health information is critical to the conduct of the study, subjects who do not provide authorization to use and disclose their health information will not be enrolled into the study. Subjects who withdraw their authorization to use and release health information during study participation will be formally discontinued from the study. The investigator may use and release at any time all the information collected prior to a subject's withdrawal of the authorization to all authorized parties to satisfy scientific, regulatory, and financial concerns.

5.6.2 Inclusion and Exclusion Criteria

Subjects' eligibility to participate in the study will be determined according to the Inclusion and Exclusion Criteria during the screening period (0 – 30 days prior to the first dose of the study drug). Subjects who ultimately do not satisfy the eligibility criteria except changing treatments and undergoing a washout period, will not be enrolled into the study. Subjects who need to meet eligibility requirements will be asked to make the necessary changes. Subjects who agree and comply will be re-evaluated prior to Baseline. Subjects who meet the requirements at screening may be enrolled the same day.

5.6.3 Demographics and Medical History

The following information will be obtained for each subject during screening: date of birth, sex, race/ ethnic origin, relevant medical and surgical history, year of diagnosis of plaque psoriasis and scalp psoriasis, and current and previous anti-psoriasis treatments within the last 6 months. All current therapies for other medical conditions will be documented. Medical history will be reviewed and updated at the Baseline Visit to ensure that the patient remains eligible to participate in the study.

5.6.4 Urine Pregnancy Test

Pregnancy testing (urine β-human chorionic gonadotrophin [β-HCG]) will be conducted in all female subjects, except those without childbearing potential (e.g., one year post-menopause, post-hysterectomy, post-bilateral oophorectomy, etc) at Screening and Baseline Visit (Week 0) prior to the first dose of Topicort®. An interim urine pregnancy test may be performed if there is reason to believe the subject may have become pregnant during the study. Subjects with a positive pregnancy test will not be eligible to participate or to continue to receive study treatment.

5.6.5 Physical Examination

A physical examination, including vital signs measurements (blood pressure and pulse), will be performed at each study visit. Any clinically significant abnormalities discovered during physical

examinations after the Screening / Baseline (if occurring on the same day) visit should be documented and evaluated as potential adverse events.

5.6.6 Investigator Global Assessment (scalp only)

Investigator Global Assessment for scalp will be determined for all subjects throughout the study. Subjects are required to have a score of 2-mild or greater to enter the study. The Investigator Global Assessment is a 5 point scale that records disease severity based on average degree of erythema, induration and scaling. Investigator Global Assessment uses a scale of 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate, and 4 = Severe. *See Appendix A*

5.6.7 Psoriasis Scalp Severity Index (PSSI) and Scalp Surface Area (SSA)

The scalp is assessed for erythema, induration and desquamation. The average degree of severity of each 3 symptoms is assigned a score of 0-4. The surface area of scalp psoriasis is then estimated as a percentage. The PSSI score is the sum of the erythema, induration and desquamation scores multiplied by the area of involvement. Scores range from 0-72. *See Appendix B*

5.6.8 Physician's Global Assessment (PGA)

PGA will be determined for all subjects throughout the study. PGA is a 5 point scale that records the overall disease severity at each clinical evaluation based on the average degree of erythema, induration, and scaling of areas affected by psoriasis. PGA uses a scale of 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate, and 4 = Severe. *See Appendix C*

5.6.9 Body Surface Area (BSA)

BSA will be determined for all subjects throughout the study. The subjects palm will be selected for the measuring unit of body surface area. The physician will equate the number of palms affected by psoriasis to derive the BSA total.

5.6.10 Patient Reported Outcomes

Subjects will complete the Subject Assessment of Pain, Itching and Scaling and Scalpdex at weeks 0, 4 and 16. Scalpdex is a self-administered quality of life instrument developed for scalp dermatitis. The 23 item survey evaluates the subject across 3 major domains –symptom, functional and emotion.[6] Pain, Itching and Scaling is a scale of 1-10 which assess pain, itch and scale in the past 24 hours. *See Appendix D and E*

5.6.11 Early Discontinuation Procedures

Subjects will be prematurely discontinued from the study under the following conditions:

1. Subject requests to withdraw from the study.
2. Subject is noncompliant with protocol schedule, restrictions, and/or requirements.
3. Subject experiences an adverse event that makes it difficult or intolerable for the subject to continue treatment, or increases risk to the subject, or interferes with the investigator's ability to clinically evaluate the progress of the subject's treatment.
4. Subject begins an unapproved concomitant therapy for psoriasis or another medical condition that may increase risk to the subject if continuing study treatment.
5. Subject cannot be reached / lost to follow-up.
6. The study investigator suspends or terminates the study.
7. Other unanticipated reason.

Any subject who prematurely discontinues the study should complete the week 16 (End of Study) assessments. Any subject who withdraws consent to participate in the study will be removed from further treatment and/or study observation immediately upon the date of request.

6 Adverse Events

6.1 Adverse Events (AEs)

An adverse event (AE) is any untoward occurrence in a subject, whether or not related to the product. An AE does not necessarily have to have a causal relationship with the study treatment. AEs include events not present at baseline and events that worsened if present at baseline. Hospitalizations for pre-treatment conditions (e.g., elective cosmetic procedures) or surgeries that were planned prior to entry into the study are not considered adverse events.

Adverse events, regardless of causality, will be captured from the signing of the Informed Consent Form and for the duration of the subject's participation.

6.2 Serious Adverse Events (SAEs)

A **serious adverse event** (SAE) is any untoward medical occurrence that meets one or more of the following criteria according to federal regulations:

a. results in death;
b. is life-threatening (the subject was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death if it were more severe);
c. results in persistent or significant disability or incapacity;
d. requires inpatient hospitalization or prolongation of existing hospitalization;
e. is a congenital anomaly or birth defect;

f. is considered an important medical event (may not be immediately life-threatening or result in death or hospitalization but may jeopardize the subject or may require intervention to prevent one of the outcomes listed in the definition above).

6.2 .1 SAE Reporting

An **Adverse Event or Suspected Adverse Reaction** is considered ‘‘serious’’ if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death;
- A life threatening adverse event; (Note: the term “life-threatening” as used here refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe);
- In-patient hospitalization or prolongation of existing hospitalization;
- A persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions);
- A congenital anomaly/birth defect;
- Any “other” important medical event.

Important medical events that may not result in death, be life-threatening or require hospitalization may be considered Serious Adverse Events when, based on appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Regardless of the above, any additional adverse events which the Principal Investigator considers significant should be immediately reported to Taro’s Drug Safety Department.

Any Serious Adverse Event, whether deemed drug-related or not, must be reported by the Investigator to the Taro’s Drug Safety Department by telephone **within 24 hours** after the Principal Investigator or Study Coordinator becomes aware of its occurrence. The Principal Investigator or the Principal Investigator’s Designee must complete a Serious Adverse Event (SAE) Form and email it to Taro’s Drug Safety Department, along with the patient’s Adverse Events Log and Concomitant Medications Log **within 24 hours** of notification of the event. When appropriate, Taro’s Drug Safety Department will notify the U.S. Food and Drug Administration (FDA) of drug related Serious Adverse Events.

Documentation of serious or unexpected adverse events and follow up information should be sent to Taro’s Drug Safety Manager within 24 hours from reporting the event by the Investigator. Following is the contact information:

Taro Drug Safety Manager:
Margo Wyatt, RN, BSN,
Drug Safety Manager, Medical Affairs
Taro Pharmaceuticals U.S.A., Inc.
Tel: 914-345-9001 Ext. 6758
Email: margo.wyatt@taro.com **and** taropvus@taro.com

Taro’s Drug Safety Department must notify FDA of fatal or life threatening adverse event as soon as possible but no later than 7 calendar days from reporting the event by the Investigator and within 15 calendar days for any other SAEs from the reporting of the event by Investigator.

The Sponsor-Investigator must inform all participating Investigators of any SAEs within 15 calendar days from reporting the event by the Investigator.

6.3 Pregnancy Reporting

The investigator will notify Taro Pharmaceuticals U.S.A. Inc. within 24 hours of discovery about any female subject who becomes pregnant after starting Topicort®. The investigator will follow the pregnancy and outcome. Any information gained will be shared with Taro Pharmaceuticals U.S.A. Inc. Female subjects who become pregnant while using Topicort® will be discontinued from study treatment.

7 INVESTIGATIONAL PRODUCT HANDLING

7.1 Investigational Product Receipt

At study initiation and as needed thereafter, Topicort® will be shipped to a responsible person at the investigator's institution, who will check the amount and condition of the drug, and maintain a record of this information. Taro Pharmaceuticals U.S.A. Inc. will instruct the Investigator on the return, disposal and/or destruction of investigational product and/or medical device materials if applicable.

7.2 Topicort Spray® Storage

Investigational product will be stored per the storage conditions identified on drug label. At the study site, all IP will be stored in a locked, safe area to prevent unauthorized access.
Records of the actual storage conditions during the period of the study will be maintained.

8 RECORD RETENTION

The investigator must retain these documents according to local laws or requirements. Essential documents include, but are not limited to, the following:

- Signed informed consent documents for all subjects;
- Subject identification code list, screening log (if applicable), and enrollment log;
- Record of all communications between the Investigator and the IRB/EC;
  Composition of the IRB/EC;
- Record of all communications between the Investigator and Taro.
- List of Sub-investigators and other appropriately qualified persons to whom the Investigator has delegated significant study-related duties, together with their roles in the study, curriculum vitae, and their signatures;
- Copies of CRFs (if paper) and of documentation of corrections for all subjects;
- IP accountability records;

- Record of any body fluids or tissue samples retained;
- All other source documents (subject records, hospital records, laboratory records, etc);
- All other documents as listed in Section 8 of the ICH consolidated guideline on GCP (Essential Documents for the Conduct of a Clinical Trial).

The Investigator must notify Taro Pharmaceuticals U.S.A. Inc. if he/she wishes to assign the essential documents to someone else, remove them to another location or is unable to retain them for a specified period. The Investigator must obtain approval in writing from Taro Pharmaceuticals U.S.A. Inc. prior to destruction of any records. If the Investigator is unable to meet this obligation, the Investigator must ask Taro Pharmaceuticals U.S.A. Inc. for permission to make alternative arrangements. Details of these arrangements should be documented. All study documents should be made available if required by relevant health authorities. Investigator/Institution should take measures to prevent accidental or premature destruction of these documents.

8.1 Study Monitoring

The investigator will self-monitor all study records for accuracy, completeness, and compliance with the protocol and GCPs and federal regulations. All study records will be made available to Taro Pharmaceuticals U.S.A. Inc. representatives upon request. Study site facilities and study records will be made available to regulatory authorities' inspectors if an inspection takes place. The investigator will notify Taro Pharmaceuticals U.S.A. Inc. if this occurs.

8.2 Statistics

It is desired to have approximately n=20 subjects at randomization. Analysis will be performed by the Investigator of Investigator Global Assessment of scalp, Psoriasis Scalp Severity Index, Scalp Surface Area, PGA x BSA and patient reported outcomes. The Investigator will also analyze SAE's.

8.2.1 Additional Statistical Considerations

Additional statistical procedures may be detailed in and performed according to a separate statistical plan at the discretion of sponsor-investigator.

REFERENCES

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8. APPENDICES

Appendix A

Investigator Global Assessment (Scalp Only)

0 – Clear Nosignsofpsoriasis.Post -inflammatory hyperpigmentationmaybepresent
1 – Almost Clear Normaltopinkcolorationoflesions,nothickening,nominimalfocal scaling
2 – Mild disease Pinktolightredcoloration;justdetectabletomildthickening, predominatelyfinescaling
3 – Moderate disease Dullbrightred,clearlydistinguishableerythema,clearly distinguishabletomoderatethickening,moderatescaling
4 – Severe disease Brighttodeepdarkredcoloration,severethickeningwithhard edges, severe/coursescalingcoveringalmostallloralllesions

Appendix B

Psoriasis Scalp Severity Index (PSSI) and Scalp Surface Area (SSA)

Psoriasis Scalp Severity Index (PSSI) and Scalp Surface Area (SSA)

Erythema (E)	**Thickening** **Plaque elevation** **Induration (I)**	**Scaling** **Desquamation (D)**	**Scalp Surface Area Score** **SSA score**
0 None	0 None	0 None	1 <10 %
1 Slight	1 Slight	1 Slight	2 10-29%
3 Moderate	3 Moderate	3 Moderate	3 30-49%
4 Severe	4 Severe	4 Severe	4 50-69%
5 Very Severe	5 Very Severe	5 Very Severe	5 70-89%
			6 90-100%

Erythema	Thickening	Scaling	Scalp Surface Area Score
☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐
1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5 6

Scalp Surface Area
Record 0-100%

_____%

Total PSSI score _____

PSSI SCORE = SUM OF SCORES FOR ERYTHEMA, THICKENING AND SCALING MULTIPLIED BY SCALP SURFACE AREA

(scores range from 0-72)

Appendix C

Physician's Global Assessment

Static Physician's Global Assessment (sPGA)

Score	Category	Description
0	Clear	**Plaque elevation** = 0 (no elevation over normal skin) **Scaling** = 0 (no evidence of scaling) **Erythema** = 0 (except for residual hyperpigmentation/ hypopigmentation)
1	Almost Clear	**Plaque elevation** = ± (possible but difficult to ascertain whether there is a slight elevation above normal skin) **Scaling** = ± (surface dryness with some desquamation) **Erythema** = ± (faint, diffuse pink or slight red coloration)
2	Mild	**Plaque elevation** = slight (slight but definite elevation, typically edges are indistinct or sloped) **Scaling** = fine (fine scale partially or mostly covering lesions) **Erythema** = mild (light red coloration)
3	Moderate	**Plaque elevation** = marked (marked definite elevation with rough or sloped edges) **Scaling** = coarser (coarser scale covering most or all of the lesions) **Erythema** = moderate (definite red coloration)
4	Severe	**Plaque elevation** = marked (marked elevation typically with hard or sharp edges) **Scaling** = coarser (coarse, non tenacious scale predominates covering most or all of the lesions) **Erythema** = severe (very bright red coloration)

Appendix D

Subject Assessment of Pain, Itching and Scaling

Select the number that best describes your scalp psoriasis symptoms during the past 24 hours

Please mark (x) one box only

Pain: Overall, how severe was your psoriasis-related pain over the past 24 hours?

No Pain ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Pain as bad as you can imagine

1 2 3 4 5 6 7 8 9 10

Itching: Overall, how severe was your psoriasis-related itch over the past 24 hours?

No Itch ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Itch as bad as you can imagine

1 2 3 4 5 6 7 8 9 10

Scaling: Overall, how severe was your psoriasis-related scaling over the past 24 hours?

No Scaling ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Scaling as bad as you can imagine

1 2 3 4 5 6 7 8 9 10

Appendix E

CONFIDENTIAL

Scalpdex

These questions concern your feelings over the past 4 weeks about **your scalp condition.** Check the answer that comes closest to the way you have been feeling.

HOW OFTEN DURING THE PAST 4 WEEKS DO THESE STATEMENTS DESCRIBE YOU?	NEVER	RARELY	SOMETIMES	OFTEN	ALL THE TIME
1. My scalp hurts	☐1	☐2	☐3	☐4	☐5
2. My scalp condition makes me feel depressed	☐1	☐2	☐3	☐4	☐5
3. My scalp itches	☐1	☐2	☐3	☐4	☐5
4. I am ashamed of my scalp condition	☐1	☐2	☐3	☐4	☐5
5. I am embarrassed by my scalp condition	☐1	☐2	☐3	☐4	☐5
6. I am frustrated by my scalp condition	☐1	☐2	☐3	☐4	☐5
7. I am humiliated by my scalp condition	☐1	☐2	☐3	☐4	☐5
8. My scalp condition bleeds	☐1	☐2	☐3	☐4	☐5
9. I am annoyed by my scalp condition	☐1	☐2	☐3	☐4	☐5
10. I am bothered by the appearance of my scalp condition	☐1	☐2	☐3	☐4	☐5
11. My scalp condition makes me feel self-conscious.	☐1	☐2	☐3	☐4	☐5
12. I am bothered that my scalp condition is incurable.	☐1	☐2	☐3	☐4	☐5
13. My scalp condition affects how I wear my hair (hairstyle, hats)	☐1	☐2	☐3	☐4	☐5
14. I am bothered by people's questions about my scalp condition.	☐1	☐2	☐3	☐4	☐5
15. My scalp condition affects the color of clothes I wear.	☐1	☐2	☐3	☐4	☐5
16. I am bothered by the persistence/reoccurrence of my scalp condition.	☐1	☐2	☐3	☐4	☐5
17. I feel stressed about my scalp condition.	☐1	☐2	☐3	☐4	☐5
18. Caring for my scalp condition is inconvenient for me.	☐1	☐2	☐3	☐4	☐5
19. I feel that my knowledge for caring for my scalp is adequate	☐1	☐2	☐3	☐4	☐5
20. The cost of caring for my scalp condition bothers me.	☐1	☐2	☐3	☐4	☐5
21. My scalp condition makes my daily life difficult.	☐1	☐2	☐3	☐4	☐5
22. My scalp condition makes me feel different from others.	☐1	☐2	☐3	☐4	☐5
23. My scalp condition makes it hard to go to the hairdresser/barber.	☐1	☐2	☐3	☐4	☐5

Appendix F
Schedule of Assessments

Procedure	Screening	Enrollment	Week 4	Week 8	Week 16
Informed Consent	X				
Demographics/Medical History	X				
Inclusion/Exclusion	X	X			
Adverse Events	X	X	X	X	X
Concomitant Medications	X	X	X	X	X
Investigator Assessments	X	X	X	X	X
Urine Pregnancy Test	X	X			
Scalpdex		X	X		X
Pain Itching Scaling		X	X		X
IP dispense/accountability		X	X	X	X

Appendix G
Dosing Diaries

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)	Remark
Ex	Jan/01	AM / PM	0800	
	Jan/01	AM / PM	1030	
1		AM / PM		
		AM / PM		
2		AM / PM		
		AM / PM		
3		AM / PM		
		AM / PM		
4		AM / PM		
		AM / PM		
5		AM / PM		
		AM / PM		
6		AM / PM		
		AM / PM		
7		AM / PM		
		AM / PM		
8		AM / PM		
		AM / PM		
9		AM / PM		
		AM / PM		
10		AM / PM		
		AM / PM		
11		AM / PM		
		AM / PM		
12		AM / PM		
		AM / PM		
13		AM / PM		
		AM / PM		
14		AM / PM		
		AM / PM		

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)	Remark
15		AM / PM		
		AM / PM		
16		AM / PM		
		AM / PM		
17		AM / PM		
		AM / PM		
18		AM / PM		
		AM / PM		
19		AM / PM		
		AM / PM		
20		AM / PM		
		AM / PM		
21		AM / PM		
		AM / PM		
22		AM / PM		
		AM / PM		
23		AM / PM		
		AM / PM		
24		AM / PM		
		AM / PM		
25		AM / PM		
		AM / PM		
26		AM / PM		
		AM / PM		
27		AM / PM		
		AM / PM		
28		AM / PM		
		AM / PM		

Extension (if needed)

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)
29		AM / PM	
		AM / PM	
30		AM / PM	
		AM / PM	
31		AM / PM	
		AM / PM	
32		AM / PM	
		AM / PM	

Subject #_____ Initials:_____

Storage
- Keep study medication at room temperature.
- Keep out of reach of children

Dosing
- Administer twice daily (approximately 12 hours apart).
- Do not apply on face, underarms or groin
- Avoid heat, flames or smoking when applying.
- Do not bandage, cover, or wrap the treated area
- Spray only enough to cover affected area and rub in.
- Avoid bathing, showering or swimming right after applying the study medication.

Dosing Diary
- Record all doses on the diary as soon as possible.
- Return diary and medication to all of your appointments.
- Record any comments or information in "remarks" section for missed dose, adverse event, or change in medication.
- Please make recordings clear and legible.

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)	Remark
Ex	JAN/01	**AM / PM**	08:30	
	JAN/01	**AM / PM**	08:00	
Ex	JAN/02	**AM / PM**	09:00	
	JAN/02	**AM / PM**	09:30	
Week 4 Day 1		**AM / PM**		
		AM / PM		
Week 4 Day 2		**AM / PM**		
		AM / PM		
Week 5 Day 1		**AM / PM**		
		AM / PM		
Week 5 Day 2		**AM / PM**		
		AM / PM		
Week 6 Day 1		**AM / PM**		
		AM / PM		
Week 6 Day 2		**AM / PM**		
		AM / PM		
Week 7 Day 1		**AM / PM**		
		AM / PM		
Week 7 Day 2		**AM / PM**		
		AM / PM		

EXT 1		**AM / PM**	
		AM / PM	
EXT 1		**AM / PM**	
		AM / PM	
EXT 2		**AM / PM**	
		AM / PM	
EXT 2		**AM / PM**	
		AM / PM	
EXT 3		**AM / PM**	
		AM / PM	
EXT 3		**AM / PM**	
		AM / PM	

Subject # _____ Initials: _____

APPLY TWO CONSECUTIVE DAYS A WEEK

Storage
- Keep study medication at room temperature.
- Keep out of reach of children

Dosing
- Administer twice daily on two consecutive days a week (e.g. Saturday and Sunday).
- Do not apply on face, underarms or groin
- Avoid heat, flames or smoking when applying.
- Do not bandage, cover, or wrap the treated area
- Spray only enough to cover affected area and rub in.
- Avoid bathing, showering or swimming right after applying the study medication.

Dosing Diary
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- Return diary and medication to all of your appointments.
- Record any comments or information in "remarks" section for missed dose, adverse event, or change in medication.
- Please make recordings clear and legible.

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)	Remark
Ex	JAN/01	**AM / PM**	08:30	
	JAN/01	**AM / PM**	08:00	
Ex	JAN/02	**AM / PM**	09:00	
	JAN/02	**AM / PM**	09:30	
Week 8 Day 1		**AM / PM**		
		AM / PM		
Week 8 Day 2		**AM / PM**		
		AM / PM		
Week 9 Day 1		**AM / PM**		
		AM / PM		
Week 9 Day 2		**AM / PM**		
		AM / PM		
Week 10 Day 1		**AM / PM**		
		AM / PM		
Week 10 Day 2		**AM / PM**		
		AM / PM		
Week 11 Day 1		**AM / PM**		
		AM / PM		
Week 11 Day 2		**AM / PM**		
		AM / PM		
Week 12 Day 1		**AM / PM**		
		AM / PM		
Week 12 Day 2		**AM / PM**		
		AM / PM		
Week 13 Day 1		**AM / PM**		
		AM / PM		
Week 13 Day 2		**AM / PM**		
		AM / PM		
Week 14 Day 1		**AM / PM**		
		AM / PM		
Week 14 Day 2		**AM / PM**		
		AM / PM		
Week 15 Day 1		**AM / PM**		
		AM / PM		
Week 15 Day 2		**AM / PM**		
		AM / PM		

	Date (MMM/DD)	Dose (Circle One)	Time (HH:MM)
EXT 1		**AM / PM**	
		AM / PM	
EXT 1		**AM / PM**	
		AM / PM	
EXT 2		**AM / PM**	
		AM / PM	
EXT 2		**AM / PM**	
		AM / PM	
EXT 3		**AM / PM**	
		AM / PM	
EXT 3		**AM / PM**	
		AM / PM	

Subject # _____ Initials: _____

APPLY TWO CONSECUTIVE DAYS A WEEK

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- Keep out of reach of children

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- Return diary and medication to all of your appointments.
- Record any comments or information in "remarks" section for missed dose, adverse event, or change in medication.
- Please make recordings clear and legible.