

██████████	Date of Visit:
Dr. ██████████	Subject ID:

Follow Up Visits

Date of Visit: _____

- Week 4
 Week 8
 Week 12
 Week 24
 Week 36
 Week 48
 Week 60
 Week 72
 Week 84
 Week 96

- Adverse Events
- Concomitant Medications
- Validated Investigator's Assessment (vIGA)
- Eczema Area Severity Index (EASI)

An "N/A" (not applicable) option was added to those activities which only occur on specific visits. Now a third party will be able to confirm that an activity was intentionally skipped.

- Tanner Staging (if applicable-Only Week 24, 48, and 72) N/A
- TB Risk Assessment Form/ TB test (Only on Week 48) N/A
- Chest X-ray (Only on Week 48-if applicable per TB Risk Assessment Form) N/A
- Vital Signs
- Physical Exam (Except week 8) N/A
- 12 Lead ECG (Only on Week 48) N/A
- Urinalysis
- Urine pregnancy test (if applicable) N/A
- Blood Draw
- PK Samples (If applicable) N/A
- Dosing Diary and Compliance Review
- Dispense Study Drug
- Dispense Home Urine Pregnancy Tests (if applicable) N/A
- ClinCard
- Scheduling
- Requisition

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Adverse Events

Where there any changes to the patient's medical status? Yes No

If yes, was adverse events chart updated? Yes No N/A **1**

1 The "N/A" (not applicable) option was added to those activities which don't apply in all situations.

Concomitant Medications

Where there any changes to the patient's medications? Yes No **2**

2 Guidance on obtaining vital signs was added to aid the coordinator.

If yes, was con meds chart updated? Yes No N/A **2**

Validated global Assessment (vIGA)

Was the assessment done? (separate form): Yes No

3 Modelling the format of the time of vital assessment ensures consistency of data.

Eczema Area and Sensitivity Index (EASI)

Was the assessment done? (separate form): Yes No

Tanner Staging (Weeks 24, 48, and 72 Only)

Was the assessment done? (separate form): Yes No N/A **1**

TB Risk Assessment Form (Only on Week 48)

Was the Risk Assessment Form completed? (separate form): Yes No N/A **1**

Chest X-ray (only if applicable per TB Risk Assessment Form)

Completed: Date/Time: _____ N/A

Vital Signs

-Obtain prior to blood collection and dosing **2**

Time of Vitals assessment (24:00): _____ **3**

Blood Pressure: _____/_____ mmHg

Was the patient sitting for three minutes before taking blood pressure? Yes No **2**
 Where was blood pressure taken (specify side and location of body): _____

Pulse: _____ beats/min

Respiratory Rate: _____ breaths/min

Temperature: _____ F C

Method of temperature collection: tympanic oral other: _____ **2**

-Ensure subject is wearing lightweight clothing and no shoes **2**

Weight: _____ lb kg

Height: _____ in cm

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Physical Exam

(Except Week 8)

No changes were made to this page.

Date: ____/____/____

Time: ____:____

Body System	Result	Abnormality
General Appearance	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Head, Neck, Ears, Nose, Throat, Eyes	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Dermatologic	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Cardiovascular	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Respiratory	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Abdomen	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Neurological	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Musculoskeletal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Extremities	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Lymph Nodes	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	
Other (specify):	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done <input type="checkbox"/> Abnormal, not clinically significant	

PI Signature: _____ Date: _____

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PK Sampling

(If dose is modified based on analysis of data from Part 2, sample will be collected prior to dosing on visit day and at subsequent visit.)

(Sample will not be collected when dose is changed due to change in subject's weight.)

Was the blood draw performed? Yes No N/A: Dose not changed since last visit **1**

Time performed: _____:_____

1
"NA" added.

Drug Return

Were kits from prior visit returned? Yes No

If yes, what kits were returned? (please specify if kits were empty when returned)

If no, was patient/guardian reminded to bring kits at next visit? Yes No N/A

2 A new question to remind staff to remind participants was added.

Dosing Diary and Compliance Review

Formulation: tablet (QD) Solution (BID) **3**

Date & Time of second to last dose: _____

Date & Time of last dose: _____

Was Dosing Diary reviewed and signed by coordinator? Yes No

Was new Dosing diary dispensed? Yes No

3 Specific questions to record dosing added.

Compliance

• (240 mg X # of bottles dispensed) = total weight of all drug beginning

240 mg X _____ = _____

• Unit variance of 1st bottle + unit variance of 2nd bottle+ etc. (for totally # of bottles)

Unit variance (drug used): weight of bottle at beginning-weight of bottle after return

_____ + _____ + _____ = _____ (total unit variance)

• Total unit variance / # of days between visit= average dose given per day

_____ / _____ = _____

• Average dose given per day / prescribed daily dose = % compliance

_____ / _____ = **_____ %**

Was drug compliance reviewed with patient/guardian of patient? Yes No

Was patient between 80% and 120% compliant? Yes No

If no, was patient re-educated on drug compliance? Yes No

4
An entire section on dosage compliance added, with significant detail regarding amount per bottle and daily dosage.

Dispense Drug **5**

Was study drug dispensed and dosing instructions reviewed? Yes No

-See dispensation confirmation and copy of dispensed kits for verification

Was there a change in patient dosing? Yes No

Was patient/guardian instructed to return all drug in possession at next visit? Yes No

Did patient/guardian verbalize understanding on compliance and dosing instructions? Yes

5
Guidance added here regarding dosage dispensation and to account for minors with parent/guardians.

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Dispense Home Urine Pregnancy Tests

(females of childbearing potential only)

Was the pregnancy tests dispensed? Yes N/A: Not of childbearing potential **1**

ClinCard Form

Was a clincard form filled out? Yes No

Scheduling

Was the next visit scheduled? Yes No

If yes, please provide day and time: _____ **2**

Requisition Form

Was the requisition form filled out? Yes No

1 The "N/A" (not applicable) option was added to those activities which don't apply in all situations.

2 Guidance added to aid the coordinator.