

64337

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	Correction
<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/>	<input type="checkbox"/>
	mm dd yyyy			

Instructions:

Expected Non-Serious Adverse Events are conditions related to treatment with Peg2a or RV/Placebo and conditions common during childhood. Answer **Yes** if the patient reported one or more of the listed symptoms since the last visit. Enter Grade 1, 2, or 3 in the **Severity** box for each reported condition.

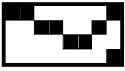
Related to Treatment with Interferon or Ribavirin/Placebo (Answer only if the condition occurred.)

	Yes	Severity	CRA Use
1. Fatigue: Lack of energy or weariness or chronically tired, in the absence of other flu-like symptoms. Characterized as prolonged weakness or tiredness that is not relieved by adequate rest, sleep, or by the removal of other stressful factors. The patient may feel rested but with daily activity feel tired or feel tired after awakening and throughout the day.	<input type="radio"/>	<input type="text"/>	ensae01s Only
2. Trouble Sleeping: Inability to sleep, to remain asleep throughout the night, or to feel refreshed by sleep.	<input type="radio"/>	<input type="text"/>	ensae02s
3. Irritability: Abnormal or excessive response to slight or harmless stimuli.	<input type="radio"/>	<input type="text"/>	ensae03s
4. Depression: One or more of the following symptoms nearly everyday during the same 2 week period, representing a change from the previous level of functioning: Depressed mood most of the day; Markedly diminished interest or pleasure in all or almost all activities; Clinically significant weight loss, in the absence of dieting, or weight gain, or a decreased appetite; Insomnia or hypersomnia; Observable psychomotor agitation or retardation; Fatigue or loss of energy; Feelings of worthlessness or excessive or inappropriate guilt; Diminished ability to think or to concentrate or indecisiveness; Recurrent thoughts of death; Recurrent suicidal ideation without a specific plan; A suicide attempt or specific plan for committing suicide; (If 5 or more of these symptoms are present, begin a Depression Management Tracking Form.)	<input type="radio"/>	<input type="text"/>	ensae04s
5. Anorexia: Loss of appetite in the absence of other flu-like symptoms.	<input type="radio"/>	<input type="text"/>	ensae05s
6. Weight Loss: Any unintentional weight loss greater than 10 % from screening.	<input type="radio"/>	<input type="text"/>	ensae06s
7. Flu-like Symptoms: These may include but are not limited to fever, cough, headache, muscle aches, chills, sweating, fatigue, congestion, sore throat, diarrhea, and loss of appetite.	<input type="radio"/>	<input type="text"/>	ensae07s
8. GI Symptoms: Including but not limited to abdominal pain, nausea, diarrhea, vomiting, and loss of appetite in the absence of other flu-like symptoms.	<input type="radio"/>	<input type="text"/>	ensae08s
9. Rash: An eruption or change in the color or texture of the skin. Symptoms are skin redness or inflammation	<input type="radio"/>	<input type="text"/>	ensae09s
10. Joint/Muscle Aches: Characterized as pain or stiffness in one or more joints or muscles, in the absence of other flu-like symptoms.	<input type="radio"/>	<input type="text"/>	ensae10s
11. Headache: Defined as pain in the head from any cause, in the absence of flu-like symptoms.	<input type="radio"/>	<input type="text"/>	ensae11s
12. Itching: Defined as a peculiar tingling or uneasy irritation of the skin which causes a desire to scratch the affected part, other than injection site reactions.	<input type="radio"/>	<input type="text"/>	ensae12s

Signature: _____

Certif. #: -

Expected Non-Serious Adverse Event



12812

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Related to Treatment with Interferon or Ribavirin/Placebo (Answer only if the condition occurred.)	CRA Use Only	
	Yes	Severity
13. <u>Injection Site Reactions</u> : Pain (without touching), tenderness (pain when area touched), itching associated with injection, bruising.	<input type="checkbox"/>	ensa^e13s
14. <u>Blood Draw Pain / Bruising</u> :	<input type="checkbox"/>	ensa^e14s

Conditions Common During Childhood (Answer only if the condition occurred.)		
	Yes	Severity
15. Otitis Media / Otitis Externa / Ear Pain :	<input type="checkbox"/>	ensa^e15s
16. URI / Cough / Congestion / Sneezing :	<input type="checkbox"/>	ensa^e16s
17. Sinusitis :	<input type="checkbox"/>	ensa^e17s
18. Conjunctivitis :	<input type="checkbox"/>	ensa^e18s
19. Constipation :	<input type="checkbox"/>	ensa^e19s
20. Dysmenorrhea :	<input type="checkbox"/>	ensa^e20s
21. Acne / Eczema / Dry Skin / Plant Related Dermatitis / Cuts / Abrasions / Bruises / Insect Bites:	<input type="checkbox"/>	ensa^e21s
22. Dental Appliances and related problems :	<input type="checkbox"/>	ensa^e22s

Signature: _____ Certif. #: [][] - [][][][]