

## HALT-C Trial

### Ribavirin Dose Adjustments

Form # 29 Q x Q Version B: 10/01/2001

**Purpose of Form #29:** The Ribavirin Dose Adjustments form records changes in the dose of Ribavirin.

**When to complete Form #29:** Form #29 should be used for recording missed doses or adjustments in the dose of Ribavirin if held doses or dose adjustments were due to the protocol or HALT-C physician's discretion.

If the Form #27 Ribavirin Accountability Log was completed with Question B1 initial dose = 0 mg, Form #29 is not required for the patient. Express patients will never require a Form #29.

Section D of Study Visit Form #10 should be used to document missed doses of Ribavirin if initiated by the patient and/or non-HALT-C personnel (such as the patient's primary care physician).

Any Ribavirin dose adjustment made before 10/01/2001 needs to be recorded on Version A of this form. Any Ribavirin dose adjustment made on or after 10/01/2001 needs to be recorded on Version B. Call the DCC to add a second version to a patient's forms in the DMS.

#### **SECTION A: GENERAL INFORMATION**

- A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

#### **SECTION B: RIBAVIRIN DOSE ADJUSTMENTS**

##### General Instructions for Section B:

For each Ribavirin dose adjustment, complete one row of Section B.

Record both increases and decreases in the dose of Ribavirin.

When Ribavirin is permanently or temporarily stopped, record the dose as 0 mg.

Record all Ribavirin dose changes, including:

- Discontinuation from previous dose to 0 mg when a Lead-In patient enters the Randomization Phase. Randomized patients do not receive Ribavirin.
- Discontinuation from previous dose to 0 mg when a Responder Phase patient complete the W48 study visit.
- Discontinuation from previous dose to 0 mg for patients with a completed Form #64 (Death) or Form #25 (Early Termination From Trial).

B1a. Date of dose change

- Record the date the Ribavirin dose was changed using MM/DD/YYYY format.

## B1b. Previous dose

- Record the previously prescribed dose of Ribavirin in mg/day.

## B1c. Dose changed to

- Record the newly prescribed dose of Ribavirin in mg/day.

## B1d. Reason dose was changed

- Record the code number of the primary reason for adjustment Ribavirin dose. Choose one Code from the list below.
- If Reason Code is 44, 5, 6, and 99, it is important to record a succinct explanation why Ribavirin dose was changed. Sixty characters, including spaces and punctuation, are provided. Examples: "Low ANC", "Neutropenia resolved", "Hct dropped", "Infection", "Depressed".

## B1e. Enter the initials of the person completing this row of Section B.

D/E column. After data entering this row, the data entry person should initial the shaded box.

**Ribavirin Dose Adjustment Codes**

- 44. Any adverse event or disabling symptom which, in the opinion of the investigator, warrants a reduction in accordance with the dose reduction guidelines outlined in the HALT-C Protocol.
- 5. Any other adverse event, which, in the opinion of the investigator, places the patient at increased risk.
- 6. Adverse event resolved.
- 7. Changed according to protocol for randomization phase, or at completion of W20 responder treatment, or Breakthrough/Relapser patients entering Randomized Phase.
- 99. Other.

### Dose Adjustment for Ribavirin

**HALT-C Trial  
Ribavirin Dose Adjustments  
Form #29 Version B: 10/01/2001**

A1. Affix ID Label Here → \_\_\_\_\_

A2. Patient Initials \_\_\_\_\_

B1

Date of dose change	Previous daily dose	Daily dose changed to:	Reason dose was changed (Use codes in table, below. For codes 44, 5, 6 and 99, explain.)	Coordinator's initials	Data entered
a.	b.	c.	d.	e.	
___/___/___	___ mg	___ mg	Explan	---	
___/___/___	___ mg	___ mg	Explan	---	
___/___/___	___ mg	___ mg	Explan	---	
___/___/___	___ mg	___ mg	Explan	---	
___/___/___	___ mg	___ mg	Explan	---	

**Ribavirin Dose Adjustment Codes**

\*44. Any adverse event or disabling symptom which, in the opinion of the investigator, warrants a reduction in accordance with the dose reduction guidelines outlined in the HALT-C Protocol. (Please explain in B1d.)

\*5. Any other adverse event, which, in the opinion of the investigator, places the patient at increased risk. (Please explain in B1d.)

\*6. Adverse event resolved. (Please explain in B1d.)

\*7. Changed according to protocol for randomization phase or at complete of W20 responder treatment.

\*99. Other. (Please explain in B1d.)

\*Complete Adverse Event Report (Form #60) or Serious Adverse Event Report (Form #61), as applicable.

HALT-C Trial Form #29 Version B: 10/01/2001 Page 1 of 1

The first row "previous dose" would always be the Initial dose of ribavirin pt received at W00.

Remember to put pt ID on every page

Any dose adjustment made before 10/01/2001 needs to be recorded on Version A of this form. Any dose adjustment made on or after 10/01/2001 needs to be recorded on Version B. Call the DCC to add a second version to a patient's forms in the DMS.

What is the dose the pt was changed to? If the ribavirin was stopped at the order of the PI, the dose should be "0".

Initials of data entry person when this part of the row is data entered.

Code from insert below.

1, maximum 2-word explanation. Codes 6 & 7 need no explanation.

Hct, Hgb, ANC, platelet reductions.

URI, depression, any other adverse events.

No explanation needed.

Use rarely!

The "dose changed to" on one row will always be the same as the next row's "previous dose".

The explanation of why the dose was adjusted is important. Be succinct: neutropenia, Hct dropped, infection, depressed. PI discretion means the PI made a clinical judgment about why the dose should be adjusted. Ask PI why and record. So, in other words, code 99, PI discretion is NOT a possible answer!

If Form #27 Ribavirin Accountability Log was completed with Question B1 initial dose = 0 mg, Form #29 is not required. Go back and check that you have completed Form # 27 on this patient.

To visualize what has been data entered, print out a report for this patient:  
Main Menu/Reports/Clinical/Ribavirin doses.