

HALT-C Trial Q x Q

Ribavirin Accountability Log

Form # 27 Version A: 06/15/2000

Purpose of Form #27: The Ribavirin Accountability Log documents the dispensation of Ribavirin to the patient and the return of all tablets from the patient. The individual documentation of trial medication dispensation and return should be completed in addition to the clinical site's pharmacy records.

When to complete Form #27: This form should be updated each time Ribavirin is dispensed to a patient or returned by a patient in the Lead-In Phase or in the Responder Phase.

- All patients who entered the Trial as Lead-In patients require a Form #27. Form #27 should be updated when ribavirin is dispensed or returned during the following study visits:
 - Lead-In Phase Visits.
 - Responder Phase Visits (ribavirin should not be dispensed during or after the Week 48 visit).
- Express patients do not require a Form #27.

Only the dispensation or return of Ribavirin is documented on Form #27. Peginterferon alfa-2a dispensation and return is documented on Form #26, Peginterferon alfa-2a Accountability Log.

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 DISPENSED AND RETURNED

- B1. Initial daily dose of Ribavirin
- For Lead-In patients, the HALT-C physician determines the initial ribavirin dosage (not more than 1200 mg per day) at the Baseline (W00) visit, as described in Section H and Appendix D of the HALT-C Protocol. Refer to the Protocol for dosing guidelines for patients with low absolute neutrophil count (ANC).
 - Circle 1 if the initial dose was 1200 mg of ribavirin per day.
 - Circle 2 if the initial dose was 1000 mg of ribavirin per day.
 - Circle 3 if the initial dose was Other than 1200 mg or 1000 mg of ribavirin per day.
 - Specify the Other dose of ribavirin in mg per day.
 - If the patient never received ribavirin, circle 3 and specify: 0 mg.

General Instructions for Column B2: Ribavirin Dispensed

For each date that Ribavirin is dispensed, complete one row of Column B2.

If no Ribavirin is dispensed at a visit, do not complete a row of Column B2.

B2a. Date Dispensed

- Record the date the Ribavirin tablets were dispensed to the patient using MM/DD/YYYY format.

B2b. # Tablets Dispensed

- Record the number of Ribavirin tablets dispensed to the patient on this date. Do not record the number of bottles. Each bottle contains 180 Ribavirin tablets.

B2c. Batch #

- Record the batch number on the bottles, which begins with "C" followed by 6 digits.
- In the unlikely event that two different batch numbers are dispensed on one day, please use two rows.

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

General Instructions for Column B3: Ribavirin Returned

For each date that Ribavirin is returned, complete one row of Column B3.

If no Ribavirin is returned at a visit, do not complete a row of Column B3.

If an empty bottle of Ribavirin is returned, complete one row of Column B3 with 0 tablets returned.

If the patient threw away or lost Ribavirin tablets, Form #926: Lost Drug Accountability. You do not need to account for Ribavirin tablets that were lost or thrown away on Form #27.

B3a. Date Returned

- Record the date the Ribavirin tablets were returned by the patient using MM/DD/YYYY format.

B3b. # Tablets Returned

- Record the number of Ribavirin tablets returned by the patient on this date. Do not record the number of bottles. Each bottle contains 180 Ribavirin tablets.
- If an empty bottle of Ribavirin is returned at a visit, record 0 tablets returned.

B3c. Batch #

- Record the batch number on the bottles, which begins with "C" followed by 6 digits.
- If two different batch numbers are returned on one day, please use two rows.

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

