



Note: Number pages sequentially (01, 02, 03) for each participant

MTN 012/IPM 010 (187)

CM-1 (423)

Participant ID

Site Number Participant Number Chk

Concomitant Medications Log

No medications taken at Screening/Enrollment. Staff Initials/Date _____

➔ Fax to SCHARP DataFax.

No medications taken throughout study. Staff Initials/Date _____

➔ End of form. Fax to SCHARP DataFax.

1. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s):
Date Started	Date Stopped	
 	 	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

2. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s):
Date Started	Date Stopped	
 	 	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

3. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s):
Date Started	Date Stopped	
 	 	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study (including the protocol-defined screening period), other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

General Information/Instructions: When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
- **Medication:** For combination medications, record the first three main active ingredients.
- **Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year are required.
- **Frequency:** Below is a list of common frequency abbreviations:

prn as needed	qd every day	tid three times daily	qhs at bedtime
once one time	bid twice daily	qid four times daily	

- Use “other, specify” for alternate dosing schedules.

- **Route:** Below is a list of common route abbreviations:

PO oral	IM intramuscular	IV intravenous	TOP topical	IHL inhaled	VAG vaginal	REC rectal
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- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).