Section 9. Study Product Considerations for Non-Pharmacy Staff

This section provides information and instructions for non-pharmacy staff related to the ordering, transport, and delivery of MTN-003 study products for study participants. Record keeping requirements for non-pharmacy staff also are provided. Associated instructions for pharmacy staff are provided in the *MTN-003 Pharmacist Study Product Management Procedures Manual*, which will be made available to each site Pharmacist of Record (PoR) by the DAIDS Protocol Pharmacist. Please also refer to related information in Sections 4 and 6 of this manual.

9.1 Responsibilities and Obligations with Regard to Blinding

MTN-003 Investigators of Record (IoRs), and by delegation all MTN-003 study staff, are responsible for maintaining the integrity of the study's blinded design. Although the assignment of participants to either oral study product or vaginal study product cannot be blinded, the identity of the specific oral or vaginal product to which each participant is assigned is double-blinded, meaning that neither study participants nor study staff — including all members of the Protocol Team — will be provided information on the identity of the specific tablets or gel to which each participant has been assigned.

Study documentation maintained by clinic staff — who are responsible for ascertaining primary and secondary study endpoints — will identify whether participants have been assigned to "oral tablets" or to "vaginal gel." Study documentation maintained by pharmacy staff — who are precluded from ascertaining primary and secondary study endpoints — will include coded information indicating the specific oral or vaginal product to which participants have been assigned. Access to study pharmacy facilities, and all study product supplies and documentation stored in these facilities, is limited to site pharmacy staff only. The IoR must ensure the security of study pharmacy facilities by empowering the MTN PoR to control access to these facilities.

Additional operational requirements to preserve blinding are as follows:

- Clinic staff should respond to participant questions about how to store product supplies, how to swallow tablets, and how to insert gel. Sample tablet bottles, gel cartons, and gel applicators should be stocked at all clinic locations for educational and counseling purposes. Actual study products may not be used for educational and counseling purposes.

- Clinic staff may observe and handle closed tablet bottles and gel cartons after dispensation by the PoR. Clinic staff may not open dispensed bottles or cartons or handle individual tablets or applicators.

- Participants will be instructed to bring all unused study product to all of their study follow-up visits.

- Participants should return their study product to the site pharmacy at the beginning of their visits. Study clinic locations should be stocked with paper bags or other suitable containers participants can use, if needed, to bring their products to the pharmacy.

- In the event that a participant reports damage or other issues or problems with her study product — not including signs, symptoms, or other adverse events associated with product use — clinic staff should refer the participant to the PoR to further discuss and evaluate her product-related concerns. Clinic staff should not inspect study product in any way and under no circumstances should clinic staff remove tablets from any bottles or dispense gel from any applicators. Similar restrictions also apply to pharmacy staff, as specified in the *MTN-003 Pharmacist Study Product Management Procedures Manual*.

  The PoR will evaluate the participant's report and respond to her questions or concerns:

  - If the participant's study product supplies have been damaged, the PoR will collect the damaged supplies from the participant (if she has brought them with her).

  - If the PoR determines that the participant requires additional instruction on how to take tablets or insert applicators, the PoR will refer the participant back to clinic staff for refresher education and counseling.

  - If the PoR identifies problems with the participant's tablets, applicators, or gel, the PoR will immediately inform the DAIDS Protocol Pharmacist of the problem and take action per instructions received from the DAIDS Protocol Pharmacist. The DAIDS Protocol Pharmacist will inform the Pharmaceutical Co-Sponsors, MTN Pharmacist, MTN CORE (FHI) Clinical Research Managers, and SDMC Project Manager of the occurrence.

  The PoR will document his/her interactions with participants, and subsequent action taken, in signed and dated notes that are retained in participant-specific pharmacy files. The PoR will forward copies of written documentation that contains no random assignment information to clinic staff to ensure timely clinic staff awareness of the resolution of participant reports. If circumstances require the PoR to dispense replacement study product supplies to a participant, the PoR will collaborate with clinic staff to obtain a newly completed MTN-003 Study Product Request Slip ordering the necessary study product supplies.

  Blinding will be maintained throughout the study and until all study endpoint data have been verified and are ready for final analysis. There are no circumstances under which it is expected that unblinding will be necessary to protect the safety of study participants. In the event that study staff become concerned that a participant may be put at undue risk by continuing use of her tablets or gel, the IoR may hold or discontinue product use by the participant; however, knowledge of the specific product to which the participant was assigned should not be necessary to guide further follow-up and/or treatment. If an IoR feels that product-specific information is necessary to protect participant safety, he/she should notify the MTN-003 Protocol Safety Review Team (PSRT).

9.2 Study Product Identification and Terminology

The six MTN-003 study products are identified as follows:

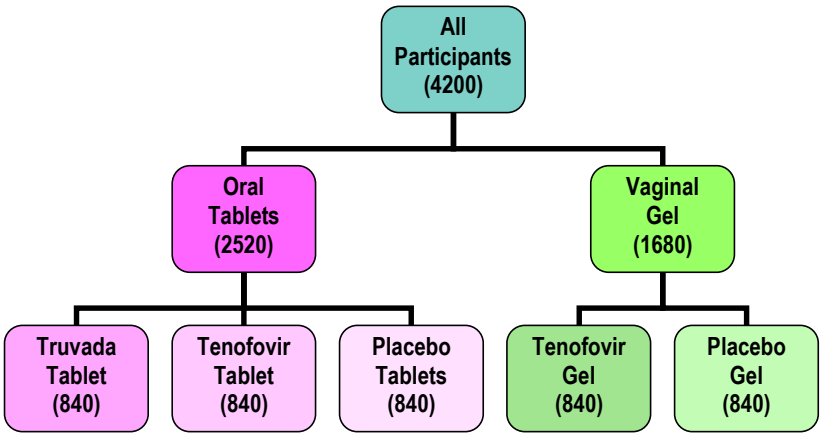
- Tenofovir disoproxil fumarate (TDF) tablet; also known by the trade name Viread®; generally referred to as "tenofovir tablet" in study educational and counseling materials; each tablet contains 300 mg TDF.
- TDF placebo tablet; generally referred to as "tenofovir placebo" in study educational and counseling materials.
- Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) tablet; also known by the trade name Truvada®; generally referred to as "Truvada tablet" in study educational and counseling materials; each tablet contains 200 mg FTC and 300 mg TDF.
- FTC/TDF placebo tablet; generally referred to as "Truvada placebo" in study educational and counseling materials.
- Tenofovir 1% gel; generally referred to as "tenofovir gel" in study educational and counseling materials; each applicator delivers approximately 4 mL of gel which contains 40 mg of tenofovir.
- Placebo gel; generally referred to as "placebo gel" in study educational and counseling materials; each applicator delivers approximately 4 mL of gel.

Please refer to protocol Section 6.3 for more information on study product formulations.

9.3 Study Product Regimens

As shown in Figure 9-1, study participants will be randomly assigned in equal numbers to one of five study groups.

Figure 9-1
MTN-003 Participant Randomization Scheme



In Figure 9-1, the five study arms are identified using the terminology used in study education and counseling materials. Corresponding to the five arms shown, participants will be assigned to one of the following study product regimens:

Truvada tablet: One FTC/TDF tablet and one TDF placebo tablet taken by mouth every day

Tenofovir tablet: One TDF tablet and one FTC/TDF placebo tablet taken by mouth every day

Placebo tablets: One TDF placebo tablet and one FTC/TDF placebo tablet taken by mouth every day

Tenofovir gel: Contents of one applicator of tenofovir 1% gel inserted vaginally every day

Placebo gel: Contents of one applicator of placebo gel inserted vaginally every day

Note: To preserve blinding, each oral tablet regimen involves taking two tablets every day.

9.4 Instructions for Inserting Study Gel and Taking Study Tablets

Participants will be instructed to insert the contents of one applicator of study gel or to swallow one of each of two different study tablets once per day, every day, until their Product Use End Visits (PUEVs). Participants also will be instructed to insert their gel or swallow their tablets as close as possible to the same time every day. If a daily dose is missed, participants will be instructed to take or insert the missed dose as soon as possible, unless the next dose is due within six hours, in which case participants will be instructed to skip the missed dose and to take the next dose as originally scheduled.

Detailed instructions for inserting gel and taking tablets are presented in Section Appendices 9-1a and 9-1b. These instructions have been translated into local languages at each site and illustrated to optimize participants' understanding of them. After first receiving these instructions at their enrollment visits, participants will complete their first product use at the clinic and then receive adherence counseling. Thereafter, product use instructions will be reinforced and adherence counseling provided at each monthly follow-up visit prior to the PUEV. Further guidance related to product use instructions, first product use, and adherence counseling is provided in Section 12 of this manual.

In the event that a participant assigned to oral study tablets vomits after taking her tablets, the following guidance should be followed:

- If a participant vomits after taking her study tablets, and is able to determine that both of her tablets have been thrown up (i.e., she can see both tablets in the vomit), she should wait approximately 30 minutes and then take another of each tablet. If this participant were to vomit again after taking the second of each tablet, she should not take any more tablets that day, but try again to take her tablets the next day, at the scheduled time of the next day's dose.

- If a participant vomits after taking her study tablets, and is not able to determine that both of her tablets have been thrown up (i.e., she cannot see one or both tablets in the vomit), she should not take any more tablets that day, but try again to take her tablets the next day, at the scheduled time of the next day's dose.

9.5 Dispensing Study Products During On-Site Visits

Please refer to Sections 4 and 6 of this manual for further information on procedures for participant randomization, initial ordering and dispensation of study products for enrolled participants, and product re-supply and re-issue during follow-up. Instructions for completing MTN-003 Prescriptions and MTN-003 Study Product Request Slips are provided in those sections.

Upon receipt of a completed and signed MTN-003 Prescription (at enrollment) or a completed and signed MTN-003 Study Product Request Slip (during follow-up), pharmacy staff will dispense study product for participants per instructions in the *MTN-003 Pharmacist Study Product Management Procedures Manual*.

Study product will be dispensed in quantities expected to be sufficient until the participant's next scheduled follow-up visit. Allowances will be made for up to a 60-day supply to be dispensed under exceptional circumstances (e.g., when a participant will not be able to attend a scheduled visit or when the minimum quantity of study product needed for daily use until the next scheduled visit is greater than the standard 30-day supply plus tablets/applicators available for re-issue). Dispensing more than a 60-day supply requires approval from the DAIDS Medical Officer (see Section 9.6 below).

- Oral study products will be dispensed in bottles containing 30 tablets each. Each bottle will contain a desiccant and will be sealed with a foil seal under the cap; caps will be child resistant. Bottles containing TDF and TDF placebo tablets will contain cotton wool. Participants should be instructed to remove the foil seal and cotton wool from the bottles but leave the desiccants inside the bottles. Oral study products expire 30 days after the bottle is opened; therefore, participants should be instructed to use the re-issued product first and then open the new bottles of study tablets.

- Vaginal gel products will be dispensed in cartons containing 10 individually-wrapped pre-filled applicators each; cartons will be sealed with tamper-evident tape. Vaginal gel products expire 60 days after dispensation; therefore, participants should be instructed to use the re-issued product first and then open the new cartons of applicators.

The PoR will label all bottles and cartons in accordance with US and local requirements. Labeling will include the PTID of the participant for whom the products were prepared and to whom they should be dispensed/delivered. Labeling will also include a "do not use after" date, which reflects the product's expiry date. For oral product, the "do not use after" date for each bottle is 30 days after the date the participant is expected to open the bottle (which may be after the date of dispensation, if tablets are re-issued). For vaginal product, the "do not use after" date is simply 60 days after carton dispensation. Participants should be instructed not to remove the labels from their bottles or cartons.

In the remainder of this section, study products prepared by pharmacy staff for dispensation to participants are referred to as "participant-specific study product."

Participant-specific study product may be dispensed to participants in one of three ways:

- From the pharmacy directly to the participant
- From the pharmacy to an authorized clinic staff member who will then deliver the bottles or cartons to the participant
- From the pharmacy to an authorized transport staff member (or "runner") who will transfer the cartons to an authorized clinic staff member who will then deliver the bottles or cartons to the participant

Each study site must designate its dispensing method in MTN-003 standard operating procedures (SOPs) for participant randomization and product re-supply during follow-up. These SOPs should be developed with input from both pharmacy and clinic staff. They must be approved by the DAIDS Protocol Pharmacist prior to study activation and may only be modified after consultation with the DAIDS Protocol Pharmacist. Further information related to each dispensing method is provided in Sections 9.5.1-9.5.3 below.

9.5.1 Dispensing from the Pharmacy Directly to Participants

At sites choosing to dispense participant-specific study product directly from the pharmacy to participants, prescriptions and product request slips are expected to be delivered to the pharmacy by the participants themselves, although this may be done by clinic staff or a runner. Upon receipt of a correctly completed and signed prescription or product request slip, the PoR will prepare the quantity of study product entered on the prescription or request slip.

9.5.2 Dispensing from the Pharmacy to Clinic Staff

At sites choosing to dispense participant-specific study product to clinic staff who will then deliver the product to participants, prescriptions and product request slips are expected to be delivered to the pharmacy by clinic staff or a runner. Upon receipt of a correctly completed and signed prescription or product request slip, the PoR will prepare the quantity of study product entered on the prescription or request slip.

The MTN-003 Record of Receipt of Participant-Specific Study Tablets (see Section Appendix 9-2a) and the MTN-003 Record of Receipt of Participant-Specific Study Gel (see Section Appendix 9-2b) must be used to document dispensing of participant-specific study product to clinic staff. For each Record of Receipt, pharmacy staff will complete the top section (CRS name, DAIDS site ID number, date) and the first four columns in the body of the record. When receiving participant-specific study product from the pharmacy, clinic staff will verify the PTIDs, confirm the quantity of product re-supplied and re-issued for each PTID (counting bottles, cartons, and packages of re-supplied applicators), and complete the remaining three columns in the body of the record for each PTID. Comments may be recorded in the designated column and, if additional space is needed, on the back of the record. All Records of Receipt will be retained in the pharmacy.

Clinic staff are responsible for controlling access to the study products dispensed into their custody and ensuring that the products are delivered to the participants for whom they were dispensed. Clinic staff also must document delivery of the products to the designated participants in the participants' study charts. Delivery may be documented in chart notes or on other source documents used for this purpose. In the event that all study products dispensed for a participant are not delivered to the participant, clinic staff will document this in the participant's study chart and return the study products to the pharmacy as soon as the participant's visit is completed.

9.5.3 Dispensing from the Pharmacy to Runners for Further Transfer to Clinic Staff

No study sites are currently planning to dispense participant-specific study product to runners who will transfer the cartons to clinic staff for subsequent delivery to participants. Should operational guidance on this method of dispensing be needed in the future, such guidance will be provided by the DAIDS Protocol Pharmacist and added to this manual.

9.6 Dispensing More Than a 60-Day Supply of Study Product

The MTN-003 protocol specifies that study products will be dispensed in quantities expected to be sufficient until a participant's next scheduled follow-up visit. The protocol allows, however, for IoRs to authorize dispensation of up to a 60-day supply under exceptional circumstances, (e.g., when a participant will not be able to attend a scheduled visit, or when the minimum quantity of study product needed for daily use until the next scheduled visit is greater than the standard 30-day supply plus tablets/applicators available re-issue). If a participant will not be able to attend two or more consecutive scheduled visits, and therefore requires more than a 60-day supply of study product, approval must be obtained from the DAIDS Medical Officer to dispense more than a 60-day supply.

Note: In the remainder of this section, reference is made to decisions made by IoRs to dispense more than a 60-day supply of study product. At sites where the IoR is not a physician, decisions to dispense more than a 60-day supply must be made by the senior research physician delegated responsibility for medical oversight of study participants.

It is expected that dispensation of more than a 60-day supply of study product will be associated with participant travel away from the study site and will be a rare occurrence. When determining whether to seek approval to dispense more than a 60-day supply, IoRs are advised to give careful consideration to participant safety, including but not limited to the following:

- The circumstances of the participant's travel away from the study site:
  - Where will the participant be?
  - Will she be with a sexual partner? If yes, what is known about the partner's HIV status?
  - How far will she be from the study site?
  - How far will she be from other sources of medical care?
  - Will she be able to store and/or use study products securely and confidentially? Will the storage temperature be consistent with protocol specifications?
  - Will it be possible for study staff to contact her either by phone or in person while she is away?

- The participant's prior history of product use:
  - How long has the participant been in the study?
  - Has she demonstrated a good understanding of proper product use?
  - Has she had adequate exposure to allow for an assessment of the likely safety of continued product use for more than one month's time?
  - Has she had any signs, symptoms, or other adverse events associated with product use? If so, what was the severity of the events and what is the likelihood they will recur?
  - If the participant were to experience an adverse event while away from the study site, what is the likelihood that she would be able to contact study staff and/or discontinue product use on her own?

- The participant's reproductive history:
  - Is the participant currently using a reliable contraceptive method? How long has she been using this method? Has her use been consistent?
  - Is the participant likely to be able to continue use of a reliable contraceptive method while away from the study site?
  - In your best judgment, how likely is the participant to become pregnant while away from the study site?

After considering all of the above, and any other relevant factors, should the IoR wish to dispense more than a 60-day supply of study product, he/she must first obtain approval from the DAIDS Medical Officer. The Medical Officer, Jeanna Piper, provides 24-hour medical coverage to the study and is available by email (piperj@niaid.nih.gov) and by telephone [+301-451-2778 (office) and +301-792-9435 (mobile)]. When requesting approval from the Medical Officer, the IoR should be prepared to provide information on the above-listed safety considerations to the Medical Officer. Upon receipt of the request, the Medical Officer will provide an immediate approval or disapproval of the request, either by e-mail or by telephone.

When requests and responses are communicated by e-mail, a print-out of the e-mail exchange will serve as documentation of the communication to be filed in the participant's study notebook. When requests and responses are communicated by telephone, within one business after the telephone communication, the IoR will prepare a written summary of the participant's circumstances, the factors leading to and supporting the IoR's request, and the date and time of the telephone call with the Medical Officer. The IoR will e-mail the written summary to the Medical Officer, and within one business day after receiving the summary the Medical Officer will reply by e-mail to document her prior verbal approval or disapproval of the request. The IoR (or designee) will print and file the correspondence in the participant's study notebook. For approvals only, the IoR also will enter a note on the MTN-003 Study Product Request Slip that he/she completes to request the required amount of study product for the participant, documenting the date and time of the Medical Officer's approval of the request.

In all cases in which more than a 60-day supply of study product is dispensed, clinic staff will obtain any available locator information from the participant and arrange to maintain periodic contact with her while she is away, if logistically possible and if contact would not jeopardize the participant's safety and confidentiality. All contacts, and contact attempts, will be documented per site SOPs. Prior to their departure from the site, participants will be counseled to contact the clinic staff if at all possible to report suspected HIV infection, suspected pregnancy, and/or any adverse events that they may experience while away.

9.7 Study Product Returns

Participants will be instructed to bring all unused study product in her possession to all follow-up visits.

- **For oral product**, participants will be instructed to return unused study tablets in the study bottles in which they were dispensed. They will also be instructed to return empty study bottles to the site in the event that all study tablets are taken prior to the next study visit. Site staff should provide specific counseling to participants randomized to oral product, to ensure that participants have a suitable plan in place to store bottles at home, including any study bottles that may be empty, for return to the study site at the next study visit.

- **For vaginal product**, participants will be instructed to return unused study applicators to the site. The return of the gel cartons in which the applicators were dispensed is preferred, but not required, due to the bulky size and difficulty transporting and storing the cartons. Site staff should provide specific counseling to participants randomized to vaginal product, to ensure that participants have a suitable place to dispose of used study applicators. If they do not have such a place and/or have concerns about disposing used applicators at home (e.g., concerns about study disclosure), site staff should instruct participants to return used applicators to the study site for disposal at their next study visit. Clinic and/or pharmacy staff should provide participants with plastic bags or other suitable containers in which to store their used applicators between visits. Clinic staff should also install easily accessible biowaste receptacles near the clinic doorway and/or in other areas within the clinic for participant use. Used applicators should then be collected from the receptacles and disposed of in accordance with applicable biowaste requirements.

Returns will be handled and documented as described in Section 6.7.1 of this manual. Returned study product may be re-issued to study participants in some circumstances, as described in Section 6.7.3 in this manual.

9.8 Study Product Retrieval

Protocol Section 9 specifies the circumstances under which use of study product may be temporarily held or permanently discontinued. Protocol Section 6.6 specifies the circumstances under which study product must be retrieved from participants who are required to hold or discontinue product use. Because participants are instructed to bring all unused study product to all follow-up visits, the need for product retrieval is expected to be rare. When product retrieval is required, retrieval may occur either by the participant returning the product to study staff or by study staff conducting outreach to retrieve the product from the participant (e.g., at her home). When product is retrieved by study staff, the retrieved product must be returned to the site pharmacy on the day of retrieval. If product is retrieved by non-pharmacy staff, as noted in Section 9.1, these staff should not open dispensed bottles or cartons or handle individual tablets or applicators.

Figure 9.2 specifies the circumstances under which study product must be retrieved, together with timeframes for retrieval.

Figure 9-2
Requirements for Retrieval of Study Product
Due To Temporary Hold or Permanent Discontinuation

	Retrieve Oral Product	Retrieve Vaginal Product
Permanent discontinuation or temporary hold due to potential HIV seroconversion	Within 24 hours*	Within 24 hours*
Permanent discontinuation due to severe (grade 3 or higher) renal or hepatic toxicity	Within 24 hours	Within 5 working days
Permanent discontinuation for any other reason	Within 5 working days	Within 5 working days
Temporary hold due to pregnancy	Within 5 working days	Within 5 working days
Temporary hold for reasons other than pregnancy with expected duration of at least 7 days	Within 7 working days	Within 7 working days

*Study product use should be held, and product retrieved if applicable, within 24 hours of first identification of a positive rapid HIV test, pending confirmation of seroconversion.

In the event that study product must be permanently discontinued due to active hepatitis B infection, the third row of Figure 9-2 should generally be followed. However, if the hepatitis B infection is associated with grade 3 or higher hepatic toxicity (e.g., grade 3 or higher AST or ALT laboratory test results), the second row of Figure 9-2 should be followed.

In addition to the specifications of Figure 9-2, under any circumstances, if a product hold extends for seven days or longer, and product has not been retrieved as of the seventh day, study staff must make every effort to retrieve all unused product within seven additional working days. For all product holds requiring product retrieval, if all product is not retrieved within timeframe listed in Figure 9-2, the PSRT must be informed.

It is not necessary to retrieve study product from participants for whom product use is temporarily held for less than seven days. However, product may be retrieved from such participants if there is concern that the participant may not comply with clinic staff instructions to refrain from product use for the duration of the temporary hold.

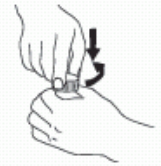
In addition to the above, all study product should be retrieved from all participants at their PUEVs. If a participant does not return all remaining unused product on the day of her PUEV, her remaining product should be retrieved within two working days. If the product is not retrieved within two working days, clinic staff must inform the PSRT and the PoR must inform the DAIDS Protocol Pharmacist.

The PoR will document all product retrievals and store retrieved product in designated areas within the site pharmacy.

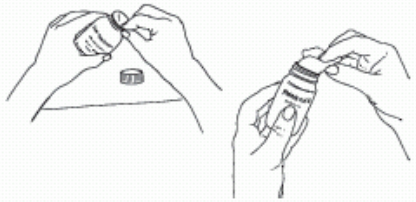
Section Appendix 9-1a
MTN-003 Tablet Use Instructions

How to Take Tablets

1. You will receive 2 bottles of tablets. One bottle is larger than the other bottle. The tablets in the larger bottle are a darker color than the tablets in the smaller bottle. Take 1 tablet from each bottle, at the same time every day.



2. After washing your hands, open the bottles by pushing the cap down while turning to the left.



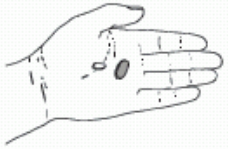
3. The first time each bottle is opened, there will be a seal covering the bottle. Remove and discard this seal. Inside the smaller bottle, there will be cotton wool. Remove and discard this cotton wool.

4. There is a sealed container inside each bottle that helps keep the tablets dry. Do not open this container, swallow it, or remove it from the bottle.

5. When taking tablets each day, first open one bottle. Remove one tablet from this bottle.

6. Then close this bottle tightly by replacing the cap and turning it to the right.

7. Next, do the same to remove one tablet from the other bottle.

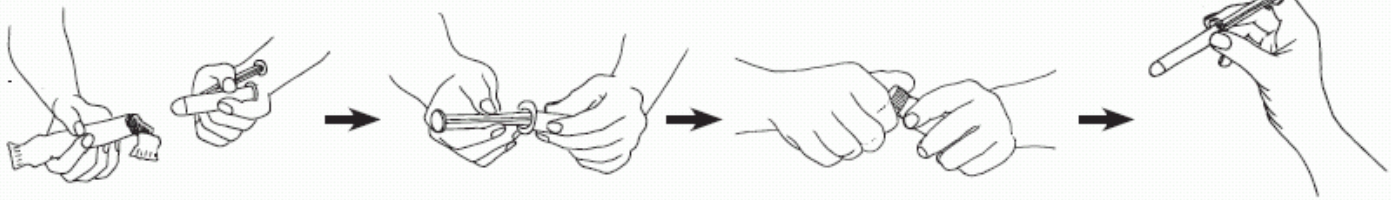


8. Now you will have one lighter tablet and one darker tablet taken from the two bottles.

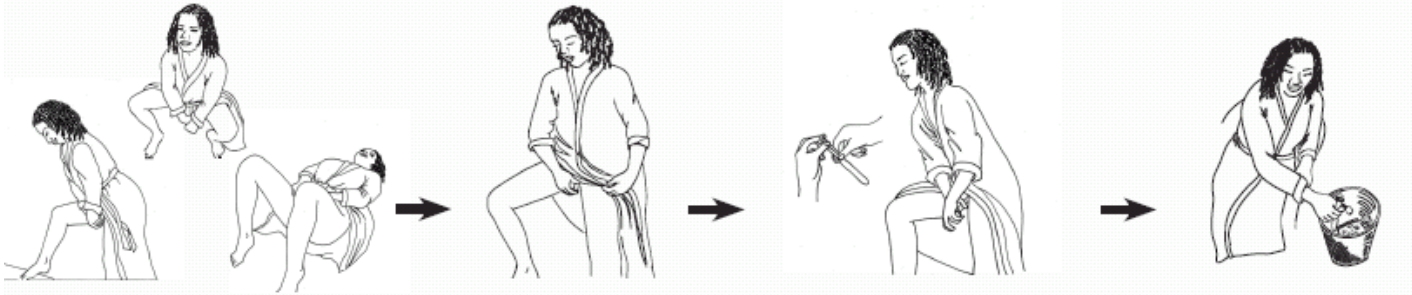
9. Put one tablet in your mouth and swallow it with water or other beverage. Then do the same with the other tablet. Or, if you wish, you may swallow both tablets at the same time.

Section Appendix 9-1b
MTN-003 Gel Use Instructions

How to Insert Gel



1. After washing your hands, tear open the wrapper. Remove the applicator and plunger.
2. Place the small end of the plunger in the hole at the back end of the applicator (opposite the blue cap).
3. Unscrew the blue cap.
4. Hold the applicator with your thumb and middle finger at the grooves on the applicator.



5. Choose a comfortable position for inserting the applicator, for example standing with one leg raised, squatting with your feet apart, or lying on your back with your knees apart.
6. Fold back the skin that covers the opening of your vagina with your other hand. Gently slide the applicator into your vagina as far as it will go comfortably or until your fingers touch your body. The plunger should stay outside your body.
7. While holding the applicator in place with one hand, push the plunger all the way into the applicator with the other hand. Or, while holding the applicator in place, use your forefinger to push the plunger all the way into the applicator.
8. After the plunger has been pushed all the way into the applicator, gently slide the applicator out of the vagina. Discard the wrapper, applicator and blue cap.

Section Appendix 9-2a
MTN-003 Record of Receipt of Participant-Specific Study Tablets

CRS Name:	**Date:**
DAIDS Site ID:	

PHARMACY STAFF				CLINIC STAFF			
PTID	# Bottles Re-Supplied	# Bottles Re-Issued	RPh Initials	Date Received by Clinic Staff	Time Received by Clinic Staff	Clinic Staff Initials	COMMENTS

Instructions: Complete one row each time participant-specific study tablets are re-supplied or re-issued to non-pharmacy staff for delivery to a study participant. All entries must be made in dark ink. Corrections may be made by drawing a single line thrrough incorrect entries, entering correct iformation, and initialing and dating the correction. Clinic staff must document delivery of all study product to designated participants in the participants' study charts.

Section Appendix 9-2b
MTN-003 Record of Receipt of Participant-Specific Study Gel

CRS Name:	**Date:**
DAIDS Site ID:	

PHARMACY STAFF				CLINIC STAFF			
PTID	# Cartons Re-Supplied	# Packages of Applicators Re-Issued	RPh Initials	Date Received by Clinic Staff	Time Received by Clinic Staff	Clinic Staff Initials	COMMENTS

Instructions: Complete one row each time participant-specific study gel is re-supplied or re-issued to non-pharmacy staff for delivery to a study participant. All entries must be made in dark ink. Corrections may be made by drawing a single line thrrough incorrect entries, entering correct iformation, and initialing and dating the correction. Clinic staff must document delivery of all study product to designated participants in the participants' study charts.