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| **PTID:** | **Visit Date:** |
| **Visit Code:** | **Staff Initials:** |

*Note: Given the frequency of the study visits, protocol counseling should be targeted per participant’s needs; not all items on this worksheet are required to be reviewed at all visits. However, at every study visit, elements listed on page 1 of this worksheet should be reviewed with the participant.*

* **Provide guidance on study requirements including prohibited practices, products and/or medications**
* Present to the study visits as scheduled.
* Contact study clinic staff if there are any questions and/or to report any issues with study product.
* Inform study staff of all medications taken during the study
* Do not take part in other research studies involving drugs, medical devices, vaccines, or genital or rectal products for the duration of study participation
* Refrain from using the following products during study participation: Heparin, including Lovenox®; Warfarin; Plavix®; hormone therapy (tablet, injectable or gel form); Aspirin (greater than 81mg); NSAIDS or any other drugs that increase the likelihood of bleeding; and CYP3A inhibitors and inducers.

**NOTE**: If participant reports use of the following products, study product must be permanently discontinued:

* + Heparin
  + Lovenox®
  + Warfarin
  + Plavix® (clopidogrel bisulfate)
  + Hormone therapy in tablet, injectable, or gel form
* All Participants: Refrain from engaging in the following activities 72 hours prior to each scheduled visit and while using study product:
* Using non-study products in the rectum and/or vagina
* Male participants: Abstain from engaging in the following sexual activities 72 hours after biopsy collection:
* Receptive anal intercourse, oral anogenital stimulation, stimulation via fingers and rectal insertion of sex toys
* Female participants: Abstain from engaging in the following activities 7 days following biopsy collection:

Inserting anything in the vagina and rectum, sexual activities including RAI, penile-vaginal intercourse, receptive oral anogenital stimulation, vaginal or rectal stimulation via fingers, and vaginal or rectal insertion of sex toys

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* **At Visit 3 and Visits 7-13, provide product adherence counseling**
* **At Visit 3:**
* Explain to participant that clinic staff will be administering the gel.
* Explain the process for gel administration
* If there is any discomfort while inserting the gel, participant should immediately inform study staff.
* **At Visits 7-13 (directly observed or staff-administered):**
* Review product use instructions with participant
* Inform participant dose administration will be directly observed or explain the process for gel administration
* Encourage the participant to ask any questions he/she may have about gel insertion
* If there is any discomfort while inserting the gel, participant should immediately inform study staff.
* **At Visit 7:**
* Provide participant with one additional pre-filled applicator of study product
* Explain to participant the purpose of this extra applicator
* Review with participant product use instructions and provide a copy of the Product Use Instructions sheet
* Provide participant an appointment card with space to record date and time of dose administration.
* Instruct participant to return unused applicator at Visit 13

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_