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| **Instructions:** Assess the participant’s baseline medical history using this guide. If the participant has any condition that is grade 1 or higher, or if determined relevant by the clinician, document on the **Medical History CRF** including the description, onset/outcome date(s), and severity grade. Add any associated medications the participant is currently taking on the **Concomitant Medications Log CRF.** | | | |
| **General Medical History** | | | |
| * Does the participant have any health problems? * Has the participant ever been hospitalized for any reason other than giving birth? * Has the participant ever had surgery, including a hysterectomy? * In the past year, has the participant been to the emergency room? * Has the participant had any medical or health problems in the past year? * Has the participant had a gynecologic or genital procedure (tubal ligation, dilation and curettage, piercing) in the last 45 days? | | | |
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| **Body System Medical History** | | | |
| Assess any significant medical problems involving the following organ/systems. | | | |
| * Head, Eyes, Ears, Nose and Throat (HEENT) * Gastrointestinal (GI) * Lymphatic * Cardiovascular * Liver * Respiratory * Renal * Musculoskeletal * OB/GYN (genital bleeding not associated with menses or childbirth, uterine fibroids, abnormal PAP, genital infection, hysterectomy e.g. uterus, at least one ovary) | * Breast * Skin * Neurologic * Endocrine/Metabolic * Hematologic * Cancer * Allergies * Mental Illness * Alcohol / Recreational Drug Use * STI/RTI (HPV, HSV, GC/CT, Syphilis, Trichomoniasis, Candidiasis, PID) * Any other health issues | | |
| **Female Symptoms/Diagnoses** | | | |
| Assess experiences of any significant medical problems involving the following organ system/disease. | | | |
| * Pelvic inflammatory disease * Genital/vaginal warts * Abnormal pap smear | | | |
| In the past 3 months ask if the participant has experienced any of the following genital symptoms. | |  |  |
| * Genital/vaginal burning | * Post-coital bleeding (bleeding after sex) | | |
| * Genital/vaginal itching | * Genital/vaginal pain not during sex | | |
| * Genital/vaginal pain during sex | * Abnormal genital/vaginal discharge | | |
| * Genital/vaginal burning | * Unusual genital/vaginal odor | | |
| * Genital/vaginal itching | * Dysuria | | |
| * Genital/vaginal pain during sex |  | | |
| Assess menstruation patterns. Document in chart notes or other site-specific form and, as applicable, on the **Medical History CRF.** | | | |
| * First and last day of last menstrual period * Any additional details as needed to describe the participant's baseline menstrual bleeding pattern   *NOTE: For the purposes of scheduling enrollment visit (if otherwise eligible), discuss when the participant anticipates her next menses to start/end, as applicable. Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-4 (Days 0, 1, and 7).* | | | |
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