

MTN-041 Frequently Asked Questions (FAQs)

This FAQ may be used by site staff to field participant questions pertaining to the vaginal ring and oral PrEP (Truvada). This document is not meant to be given directly to study participants.

VAGINAL/DAPIVIRINE RING	
What is a vaginal ring?	<ul style="list-style-type: none"> • Vaginal rings are flexible products that fit high up inside the vagina and allow for the slow, continuous release of a drug or multiple drugs over a period of weeks or months. In the U.S. and Europe, vaginal rings are licensed for both contraception and hormone replacement. Women can insert and remove the ring themselves.
What is dapivirine?	<ul style="list-style-type: none"> • Dapivirine is the medication added to the ring. It is being used to prevent HIV.
What is the dapivirine ring?	<ul style="list-style-type: none"> • The ring is a flexible product that when placed inside the vagina, slowly releases an anti-HIV medicine called dapivirine. The medicine is released where it is needed to prevent HIV from vaginal sex – the vagina. Most of the drug stays in the vagina; only a small amount of the medicine gets into the blood stream and is absorbed in the body. The ring is used for a month at a time.
Can you get HIV from the dapivirine ring?	<ul style="list-style-type: none"> • No, you cannot get HIV from the ring. The medication in the ring works to prevent HIV from establishing infection inside the body.
How safe is the dapivirine ring for use during pregnancy and breastfeeding?	<ul style="list-style-type: none"> • The medicine, dapivirine, that is released from the ring to protect against HIV stays mostly in the vaginal area and only a very small amount of dapivirine is absorbed into the mother's body and transferred into her breastmilk. • Based on what is known, researchers estimate that breastfeeding infants may only be exposed to very low levels of the drug. • Animal studies have raised no concerns about the safety of the ring for use during pregnancy and breastfeeding. • Because little is known about the effects of dapivirine on a woman's pregnancy or her baby, women who took part in studies of the ring were required to be on contraception. Even so, some women did get pregnant, and they stopped using the ring as soon as they learned they were pregnant. These women had normal pregnancies and healthy babies, and this is encouraging. • Now researchers are planning studies that will look to understand whether the ring is safe for women to use the entire time they are pregnant and for those who are actively breastfeeding.
Is the dapivirine ring difficult to insert and remove?	<ul style="list-style-type: none"> • To date, most women find the ring easy to insert and remove.
Who inserts and removes the dapivirine ring?	<ul style="list-style-type: none"> • Women can insert and remove the ring themselves. • In some studies, the clinician inserted and removed the ring for the participant. Some women may prefer that the ring be inserted by a clinician.

Frequently Asked Questions (FAQs)

Does the dapivirine ring cause pain during sex?	<ul style="list-style-type: none"> • Most women and their partners do not feel the ring in the vagina during sex nor experience any discomfort or pain. It is safe to leave it inserted during sex.
What does the dapivirine ring feel like when it is inserted?	<ul style="list-style-type: none"> • Most women do not feel the ring once it's in place. Like a tampon, the ring can be adjusted once inserted so that it does not cause discomfort.
Is it safe to leave the dapivirine ring inserted for a month?	<ul style="list-style-type: none"> • Yes. Studies have shown that the ring is safe to leave inserted for a month – or even a bit longer. Also, researchers are testing a ring that is intended to be used for 3 months at a time.
If a woman uses the dapivirine ring, will she be able to get pregnant in the future?	<ul style="list-style-type: none"> • The dapivirine ring has not been found to have any effect on a woman's ability to become pregnant during or after use.
Why offer dapivirine rings to pregnant and breastfeeding women?	<ul style="list-style-type: none"> • Pregnant and breastfeeding women living in settings where HIV is common often remain at high risk of HIV acquisition during pregnancy and breastfeeding. Changes in a woman's body during pregnancy and breastfeeding may make it easier for her to acquire HIV if she is exposed to it. Social and behavioral factors (such as her partner having other partners) may increase her chance of exposure to HIV infection, as well. • Women who acquire HIV while pregnant and breastfeeding have a greater risk of transmitting HIV to their infants than women who become infected with HIV before pregnancy or breastfeeding.

MTN-041

Frequently Asked Questions (FAQs)

Oral PrEP/TRUVADA TABLET	
What is oral PrEP?	<ul style="list-style-type: none"> Oral Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy by which HIV-negative individuals take a medication every day to reduce their risk of becoming infected. The medication work to prevent HIV from establishing infection inside the body. Oral PrEP has proven effective in clinical trials and has been approved for use in many countries.
What drugs are being used for oral PrEP?	<ul style="list-style-type: none"> Currently, Truvada is the only approved drug for oral PrEP. There are studies underway to explore other drug options.
How effective is oral PrEP at preventing HIV?	<ul style="list-style-type: none"> If taken correctly and consistently, oral PrEP is highly effective in reducing the risk of acquiring HIV. For women especially, it is essential to take oral PrEP every day to get full protection.
Is oral PrEP safe for use during pregnancy and breastfeeding?	<ul style="list-style-type: none"> If a woman takes oral PrEP, her baby will be exposed to the drugs, but this does not appear to increase the chance of birth defects. Based on what is known, WHO says PrEP is safe for pregnant and breastfeeding women. In oral PrEP studies, no health problems have been associated with oral PrEP use by women in early pregnancy or for their babies. An upcoming MTN study plans to evaluate the safety of oral PrEP in pregnant women in four African countries.
Why offer oral PrEP to pregnant and breastfeeding women?	<ul style="list-style-type: none"> Pregnant and breastfeeding women living in settings where HIV is common often remain at high risk of HIV acquisition during pregnancy and breastfeeding. Changes in a woman's body during pregnancy and breastfeeding may make it easier for her to acquire HIV if she is exposed. Social and behavioral factors (such as her partner having other partners) may increase her chance of exposure to HIV infection, as well. Women who acquire HIV while pregnant and breastfeeding have a greater risk of transmitting HIV to their babies than women who become infected with HIV before pregnancy or breastfeeding.
Can you get HIV from Truvada for oral PrEP?	<ul style="list-style-type: none"> No, you cannot get HIV from Truvada. The medications in Truvada work to prevent HIV from establishing infection inside the body.