



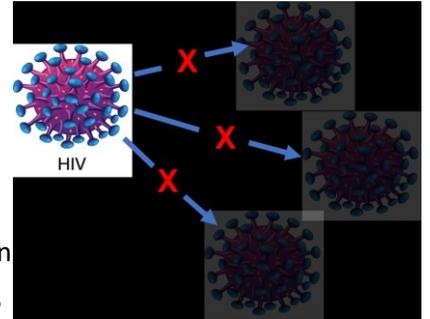
About the Dapivirine Vaginal Ring



The dapivirine ring is worn in the vagina and replaced monthly. It contains an ARV drug, dapivirine, that can prevent the woman from getting HIV if exposed during vaginal sex.

How does the ring work?

When the ring is in the vagina, the drug dapivirine is slowly released over the course of one month. Dapivirine works by preventing HIV from making copies of itself and infecting the body.



Studies have shown the ring can offer protection from HIV infection.

Women who used the ring continuously had the highest levels of protection



How do you use the ring?

- The ring is soft and flexible. It is easy for women to insert and remove from their vagina using their fingers. The ring sits high up in the vagina where it cannot be felt.
- The ring is left in place continuously for a whole month, then removed and replaced with a new ring.
- The ring can slip out but this is not common. If this happens, women can rinse the ring in water and reinsert it.

Will the ring impact daily life?

- The ring should remain in during daily activities, including bathing, menses, sex, and health checkups.
- Most women do not feel the ring if inserted properly nor do their partners feel it during sex.
- Women may feel reassured knowing that use of the ring may protect her and her baby from getting HIV.

Study participants will be taught how to insert and remove the ring. Study staff can help them as needed.

Is the ring safe for women?

- The ring has been studied in women who are not pregnant or breastfeeding and shown to be safe and effective for those who wear it continuously. Regulatory groups are reviewing results from previous ring studies to potentially approve it for public use.
- Most women experience few to no side effects from the ring. The ring does NOT: change the size or shape of the vagina, cause cervical cancer, impact fertility, or cause other significant health problems.

What about for breastfeeding women?

- Side effects may differ in breastfeeding women, or they may be similar to the side effects experienced by women who are not breastfeeding.
- This is the first study to look at used of the ring by breastfeeding women. Therefore, there may be some risk to breastfeeding mothers and their babies exposed to the drug through the mother's milk that are not yet known.
- A small study in the United States enrolled women who had already weaned their infants but were still able to produce breastmilk. There were no safety concerns and the study found that only very small amounts of dapivirine got into breastmilk.
- There is currently no reason to suspect that using the ring will change the amount of breast milk produced, its nutritional value, or its taste.
- **More safety information is needed, that is why B-PROTECTED is being done.**



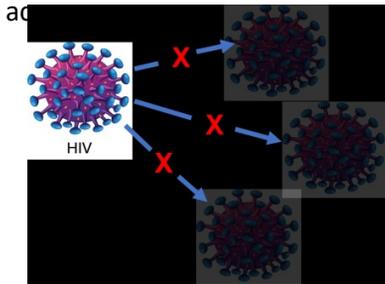
About Oral Truvada



Oral Truvada, also called PrEP, is a pill taken daily that contains ARV drugs to prevent the man or woman taking it from getting HIV if exposed.

What is PrEP?

PrEP stands for pre-exposure prophylaxis. It is a strategy for HIV-negative people to prevent HIV. Oral Truvada is a type of PrEP and is a pill that contains two anti-retroviral (ARV) drugs inside each tablet. Oral Truvada may be available in the community outside of this study. Study staff can provide more information about potential



How does oral Truvada work?

When oral Truvada is taken daily, the ARV drugs are released from the pill and circulate in the body. The drugs work by preventing HIV from making copies of itself and infecting the body. Truvada can reduce the risk of HIV infection up to 90% if taken everyday.

How do you use oral Truvada?

- Oral Truvada is a pill taken once daily by mouth
- The pills should be taken with water or another non-alcoholic beverage, they do not need to be taken with food.

Study participants will be counseled on how to swallow pills and strategies to take oral Truvada every day.



Is oral Truvada safe?

- Oral Truvada is approved for preventing HIV in adults and adolescents. It is also approved for *treating* HIV in people 12 years and older, in combination with other drugs.
- Most side effects are mild and go away shortly after starting use (for example, headaches, stomach pain)
- Serious side effects, although rare, include rash, kidney damage, bone pain, allergic reaction. People with Hepatitis B who suddenly stop using Truvada may get a flare or worsening hepatitis symptoms.

What about for breastfeeding women?

- Side effects may differ in breastfeeding women, or they may be similar to the side effects experienced by women who are not breastfeeding.
- The World Health Organization (WHO) recommends oral Truvada for treatment of HIV infection during breastfeeding and it is generally considered safe.
- Small studies of healthy HIV-negative breastfeeding women with Truvada used for prevention also show no safety concerns to either the mother or baby; babies were exposed to very low levels of the drug through breastmilk.
- There is currently no reason to suspect that oral Truvada will change the amount of breast milk produced, its nutritional value, or its taste.
- **More safety data are needed, that is why B-PROTECTED is being done.**

For more information about B-PROTECTED, go to: <http://www.mtnstopshiv.org/news/studies/mtn043>

Contact study staff at <clinic name> <staff name, phone number>