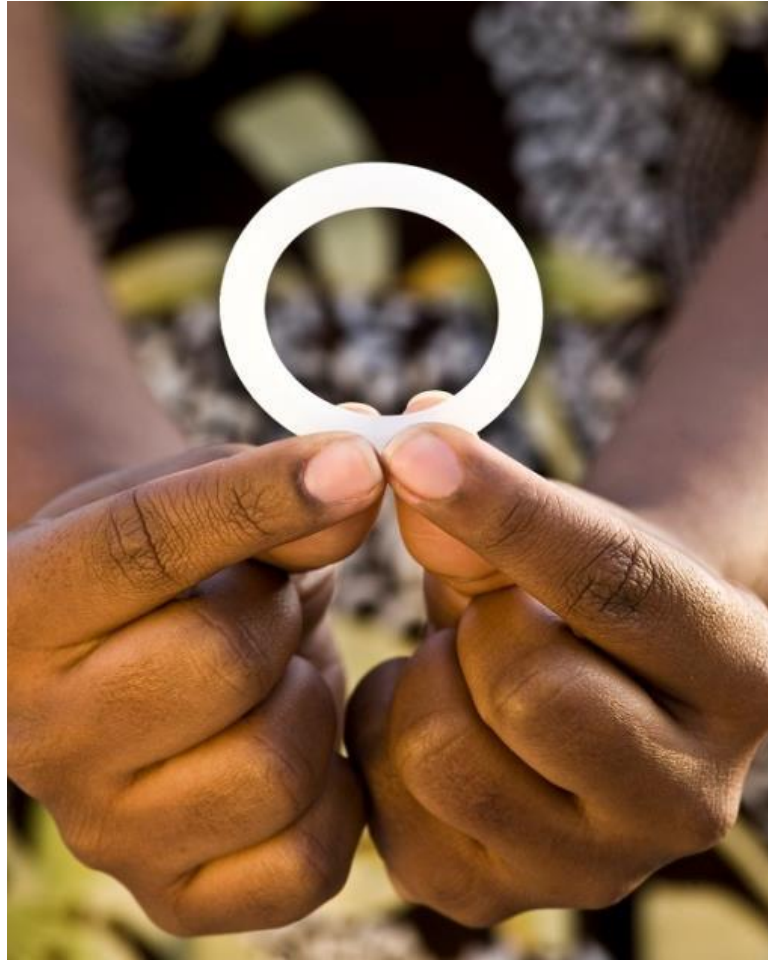


A RING TO PROTECT WOMEN FROM HIV

IPM's Monthly Dapivirine Ring

“IPM’s most advanced product is a monthly vaginal ring that slowly releases the antiretroviral (ARV) drug dapivirine to prevent HIV”

The ring!



More about the Ring

- The novel ring adapts a common medical technology — a vaginal ring — to be used in the fight against HIV.
- The ring would address a critical gap in current prevention strategies by offering long-acting female-initiated protection against HIV.
- This is particularly important for women in developing countries, where the epidemic has hit hardest, particularly young women, who are at least twice as likely to be infected as young men.
- IPM's dapivirine ring is easy to use, and is designed to remain in place for a month at a time to provide sustained protection against HIV.

More about the Ring

- Given the ring's promise, the US National Institutes of Health-funded Microbicide Trials Network (MTN) partnered with IPM to advance this important product into parallel late-stage clinical trials.
- IPM and MTN, now IPM's clinical trial partner, are each studying the ring in concurrent Phase III studies that together evaluate the ring's efficacy and long-term safety in women in four African countries.
- Because two Phase III trials are required for regulatory approval, conducting them simultaneously may help us shorten the time line to approval for this urgently needed product

Benefits of the Ring: Discreet and long-acting

- The ring has tremendous potential as a new HIV prevention method. It could offer discreet and long-acting protection against HIV.
- Because the monthly ring is convenient and easy-to-use, it may be easier for women to use it consistently — necessary for any prevention tools to be effective.
- Efforts are underway to ensure that future manufacturing costs of the ring are kept as low as possible. Affordability, along with the product's known acceptability among women and their partners, could make the ring a practical HIV prevention option for women in developing countries — and around the world.

The Active Ingredient: Dapivirine

Dapivirine belongs to the same class of ARVs being used successfully to treat HIV/AIDS and prevent mother-to-child transmission.

- Dapivirine is a type of ARV drug known as a non-nucleoside reverse transcriptase inhibitor (or NNRTI), and works by preventing HIV from replicating inside a healthy cell.
- Janssen Sciences Ireland UC, a Janssen pharmaceutical company of Johnson & Johnson, first tested dapivirine in oral formulations in 11 safety studies before 2004 and later partnered with IPM, which has tested dapivirine as a vaginal gel or ring in 16 safety studies.

The Ring: Acceptability and Safety

- ARVs can prevent HIV in women when they are used consistently.
- No matter how well-designed a product may be, it is essential that it fits women's needs and lifestyles so it is used consistently. IPM takes women's preferences into account from the earliest stages of product development.

High acceptability

- To ensure that the ring would meet the needs of women who are at greatest risk of HIV, IPM conducted a study to assess the acceptability and safety of a placebo ring (containing no active drug) among women in South Africa and Tanzania.
- Results from this study showed that the ring is acceptable to women and nearly all women expressed an interest in using the ring if proven effective against HIV.
- While some indicated interest in using it discreetly, the majority of women preferred to involve their partner. Male partners who were interviewed also supported use of the ring.

Safe for use:

- The results from an additional safety and acceptability study conducted in four countries in Africa showed the dapivirine ring to be safe and well-tolerated by women in the trial.
- Women overwhelmingly found the ring acceptable to use and expressed interest in using it for HIV prevention.
- IPM has completed seven additional safety studies of different ring formulations, all of which support the ring's safety and tolerability.

The Ring as a Platform Technology

- We are applying our expertise in ring development to create a multipurpose prevention technology that combines an ARV with a contraceptive hormone to address women's HIV prevention and reproductive health needs.
- This 90-day dapivirine-contraceptive ring is set to enter a Phase I trial in 2015. IPM is also adapting the ring to deliver multiple ARVs that target HIV at different points in its life cycle, which could potentially provide greater protection than a single drug alone.

Offering Hope with New Prevention Technologies

- HIV/AIDS is one of the greatest threats to women's health globally, which is why women urgently need self-initiated, practical prevention tools they can and are willing to use.
- IPM's monthly dapivirine ring offers promising advantages, including its long-acting duration, affordability and the ability to deliver the drug where it is needed locally, with low systemic absorption.
- Rings and MPTs promise to empower women to protect their health — and, in turn, that of their families and communities.