dapivirine Vaginal Ring

WHAT IS THE DAPIVIRINE VAGINAL RING?

The dapivirine vaginal ring is a flexible vaginal ring made of silicone that slowly releases an antiretroviral medication (ARV) called dapivirine over the course of one month to reduce the risk of HIV infection. The ring was developed by the non-profit International Partnership for Microbicides (IPM).

The dapivirine vaginal ring received a positive scientific opinion in July 2020 for use by cisgender women and other people assigned female at birth (AFAB) ages 18 and older from the European Medicines Agency (EMA), a stringent regulatory authority. The EMA is a decentralized agency of the European Union (EU), responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU.

The monthly ring is the first long-acting HIV prevention product and is designed to help address unmet need among AFAB people for new methods given the persistently high rates of HIV they face, especially in sub-Saharan Africa.

MORE ABOUT VAGINAL RINGS

Vaginal rings are small, flexible plastic rings that are inserted into the vagina to release different drugs to help achieve sexual and reproductive health goals, including contraception, hormone management, and HIV prevention.

Vaginal rings are already used successfully in many countries to deliver contraception.

HOW DOES THE DAPIVIRINE VAGINAL RING WORK?

Vaginal rings provide controlled release of drugs over extended periods of time. IPM's ring is a novel formulation made of flexible silicone with 25mg of the ARV drug dapivirine dispersed uniformly throughout its matrix (56mm outer diameter, 7.7mm cross-sectional diameter). The ring slowly delivers the drug directly to the site of potential infection over a month, with low systemic exposure, which could help minimize side effects.

Dapivirine belongs to the same class of ARVs used to successfully treat HIV/AIDS and prevent perinatal transmission. Known as a non-nucleoside reverse transcriptase inhibitor (NNRTI), dapivirine works by blocking HIV from replicating inside a healthy cell.

IS THE DAPIVIRINE VAGINAL RING SAFE?

No safety concerns related to the dapivirine ring have been identified in clinical trials. The ring delivers dapivirine locally in the vagina where infection could occur and little of the drug is absorbed elsewhere in the body.

Data from Phase III studies show no evidence that the ring increases resistance to NNRTIs or interferes with treatment response among AFAB people who became HIV-positive during clinical trials.

Mild side effects have been reported. Some participants of clinical trials experienced mild to moderate urinary tract issues and vaginal discharge or itching, but these usually went away within 1-2 weeks.

The ring can be used with most family planning methods. An ongoing open-label study among pregnant people is collecting additional safety data about ring use during pregnancy. An additional study is planned to assess safety of ring use while breastfeeding. Read more about HIV among pregnant people.

IS THE DAPIVIRINE VAGINAL RING EFFECTIVE?

The dapivirine vaginal ring reduced the risk of HIV infection by 35% in The Ring Study and by 27% in the ASPIRE study.

In addition, recent open label studies showed greater adherence to the ring and modeling data suggest that HIV risk is reduced by about 50%. Increased ring use was associated with greater HIV risk reduction.

IS THE DAPIVIRINE VAGINAL RING EASY TO USE?

The ring can be inserted by AFAB people without help from a healthcare provider. A healthcare provider may insert the first ring, if wanted, to ensure that the user is familiar with how the ring should be inserted. The ring can be stored, inserted, and removed in private.

The majority of participants in clinical trials reported that the ring didn't interfere with their daily activities or cause any pain. Most participants in Phase III studies reported forgetting the ring was in place, and that neither they nor their partner could feel it during sex.

The dapivirine ring provides steady release of drug over one month without the need for maintenance. Low maintenance means less burden on the user to remember doses and may encourage more consistent use. Although the ring should be used consistently–that means it should be kept inside the vagina for the entire month of use–the ring does not have any visual indicators to show that dapivirine is being released.

RING STATUS AND NEXT STEPS

Regulatory: The dapivirine ring received a positive scientific opinion in July 2020 from the EMA for use among AFAB people ages 18 and older in developing countries. The product was also prequalified by the World Health Organization (WHO) in November 2020 and received a WHO recommendation in January 2021. IPM is seeking country regulatory approvals in sub-Saharan Africa. The ring is also currently under review by the U.S. Food and Drug Administration (FDA).

In parallel, IPM will also conduct additional research to better understand the ring's efficacy among AFAB people ages 18-25. IPM has been working across sectors to prepare for the ring's possible introduction.

Guidelines about ring use (such as what kinds of regular testing is needed to use the ring and whether a ring can be prescribed by a nurse or clinician) will be determined by each country. The WHO will also issue guidelines on ring use.

Research: A safety study of the ring is ongoing in Africa by the MTN among adolescent girls and young women (REACH), which may support future regulatory approvals. MTN is also conducting safety studies among pregnant women (DELIVER) and breastfeeding women (B-PROTECTED), both in Africa, to help us understand how the ring could fit into the lives of these key groups.

Other types of rings are in development as well:

- Long-acting rings that can be worn for up to 90 days
- Multipurpose rings with dapivirine and/or other ARVs that prevent HIV plus additional medications to prevent sexually transmitted infections (STIs) and/or unwanted pregnancy.

Multi-purpose technologies will help meet AFAB people's needs, increase synergy of family planning and HIV prevention services, and reduce barriers to acceptability and access. While these products and other HIV prevention technologies are still in development, the monthly dapivirine vaginal ring will help pave the way for their introduction.

THE BOTTOM LINE

The dapivirine vaginal ring presents an additional option for cisgender women and other Assigned Female at Birth (AFAB) people who want to protect themselves from HIV. As the family planning field has shown, more options can lead to higher uptake of prevention methods overall.

Further trials are planned and underway to gather more data on the safety of ring use during adolescence, pregnancy, and breastfeeding.

The dapivirine ring marks the first time a vaginal ring has been shown to deliver an ARV for HIV prevention. If approved, the ring would offer cisgender women and other AFAB people the first long-acting tool they can control themselves and use discreetly to reduce their HIV risk.

MORE INFORMATION

IPM: Dapivirine Ring

IPM: The Ring Study

AVAC: Dapivirine Ring Results

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