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Dapivirine Vaginal Ring 25 mg (*dapivirine*)

An overview of Dapivirine Vaginal Ring 25 mg and why it received a positive opinion

What is Dapivirine Vaginal Ring 25 mg and what is it used for?

Dapivirine Vaginal Ring 25 mg is a vaginal ring used to reduce the risk of a woman getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse.

It is for use with safer sex practices (such as use of condoms) by adult and adolescent women aged 16 years and older, when taking pre-exposure prophylaxis (PrEP) medicines by mouth is not feasible. It is intended for use [outside the EU](#).

Dapivirine Vaginal Ring 25 mg contains the active substance dapivirine.

How is Dapivirine Vaginal Ring 25 mg used?

Dapivirine Vaginal Ring 25 mg is a silicone ring that is inserted into the vagina and slowly releases dapivirine, an antiviral medicine, over the course of one month. The ring should be removed after four weeks of use, and replaced straight away with a new ring.

Arrangements for supply of the medicine will be the responsibility of national medicines regulators. For more information about using Dapivirine Vaginal Ring 25 mg, see the package leaflet or contact your healthcare provider.

How does Dapivirine Vaginal Ring 25 mg work?

The active substance in Dapivirine Vaginal Ring 25 mg, dapivirine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows the virus to make more copies of itself in the cells it has infected and to spread in the body. By blocking reverse transcriptase, dapivirine, which is released from the silicone ring at the site of potential infection in the vagina, stops the virus from multiplying and spreading in the body if the woman is exposed to the virus.



What benefits of Dapivirine Vaginal Ring 25 mg have been shown in studies?

A main study conducted in almost 2,000 women from 18 years of age in sub-Saharan Africa showed that 4.2% of women who used Dapivirine Vaginal Ring 25 mg became infected after two years of treatment, compared with 6.4% of women who used placebo (a vaginal ring not releasing any medicine). This means that Dapivirine Vaginal Ring 25 mg lowered the chances of being infected with HIV-1 by over a third (35.1%).

Another study in 247 young adult and adolescent women from 16 to 21 years of age supported the use of Dapivirine Vaginal Ring 25 mg in this age group. The study found that the level of dapivirine remaining in the ring (and therefore the amount released from it) after 1 month of use was similar to that seen in adult women. The observed side effects were also in line with those observed in the main study.

What are the risks associated with Dapivirine Vaginal Ring 25 mg?

For the full list of side effects and restrictions with Dapivirine Vaginal Ring 25 mg, see the package leaflet.

The most common side effects with Dapivirine Vaginal Ring 25 mg (which may affect more than 1 in 20 people) are urinary tract infection (infection of the structures that carry urine), vaginal discharge, vulvovaginal pruritus (itching), vulvovaginitis (inflammation or irritation of the skin of the vulvar and vaginal area) and pelvic (lower belly) pain.

Dapivirine Vaginal Ring 25 mg must not be used by women with unknown or positive HIV status.

Why did Dapivirine Vaginal Ring 25 mg receive a positive opinion?

At the time of authorisation, there were some uncertainties about the risk of resistance and the benefits in younger women in particular, which is being addressed in a further study. Overall, however, Dapivirine Vaginal Ring 25 mg was shown to be moderately effective at lowering the risk of HIV-1 infection following vaginal intercourse in adult women, and its side effects are considered manageable. Further data also support its use in adolescents aged 16 years and older. The European Medicines Agency therefore decided that its benefits are greater than its risks in women 16 years of age and older who are not using PrEP medicines by mouth.

What measures are being taken to ensure the safe and effective use of Dapivirine Vaginal Ring 25 mg?

The organisation that markets Dapivirine Vaginal Ring 25 mg is conducting a study in women between 18 and 25 years of age to address the current uncertainty regarding effectiveness in younger women and the development of resistance in women who become HIV positive, and to confirm the overall effect of the medicine.

The organisation will also provide educational materials to healthcare professionals expected to prescribe and dispense the medicine and a user guide for women, with information on the safety of the medicine, the importance of compliance during treatment and how to use the medicine correctly.

Recommendations and precautions to be followed by healthcare professionals and women for the safe and effective use of Dapivirine Vaginal Ring 25 mg have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dapivirine Vaginal Ring 25 mg are continuously monitored. Side effects reported with Dapivirine Vaginal Ring 25 mg are carefully evaluated and any necessary action taken to protect patients.

Other information about Dapivirine Vaginal Ring 25 mg

The European Medicines Agency gave a positive opinion for Dapivirine Vaginal Ring 25 mg on 23 July 2020.

The Agency assessed Dapivirine Vaginal Ring 25 mg as part of its [cooperation with the World Health Organization](#), whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Dapivirine Vaginal Ring 25 mg can be found on the Agency's website: ema.europa.eu/dapivirine-vaginal-ring-25mg-h-w-2168.

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