

Package leaflet: Information for the user

Dapivirine Vaginal Ring 25 mg vaginal delivery system

dapivirine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare provider.
- This medicine has been prescribed for you only. Do not give it to others as it may harm them.
- If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dapivirine Vaginal Ring is and what it is used for
2. What you need to know before you use Dapivirine Vaginal Ring
3. How to use Dapivirine Vaginal Ring
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1. What Dapivirine Vaginal Ring is and what it is used for

The Dapivirine Vaginal Ring is used to reduce the chance of women 18 years and older getting a HIV-1 infection during vaginal sex. It should always be used in combination with safer sex practices and should be used when oral PrEP is not/cannot be used or is not available.

The Dapivirine Vaginal Ring contains dapivirine, a medicine that can reduce the risk to become HIV-1 infected.

The medicine is released from the ring into the vagina slowly over one month.

The Dapivirine Vaginal Ring must be kept in the vagina all the time until it is replaced with a new ring after one month.

The Dapivirine Vaginal Ring is an off-white coloured ring that is easy to bend and should only be used in the vagina.

Ask your healthcare provider if you have any questions about how to prevent getting HIV infected or how to prevent spreading HIV to other people.

2. What you need to know before you use Dapivirine Vaginal Ring

Do not use Dapivirine Vaginal Ring:

- If you are infected with HIV-1 or you are unsure if you are infected with HIV-1. You must get tested to make sure that you do not already have HIV-1 infection. The Dapivirine Vaginal Ring can only help to reduce the chance of you getting HIV-1 **before** you are infected.

- **Some HIV tests may miss a recent infection in the early stages.** If you get a flu-like illness, it could mean you have recently been infected with HIV. The following may be signs of HIV infection:
 - tiredness
 - fever
 - joint or muscle pain
 - headache
 - vomiting or diarrhoea
 - rash
 - night sweats
 - enlarged glands in the neck or groin
- **Tell your healthcare provider about any flu-like illness** – either in the month before starting to use the Dapivirine Vaginal Ring, or at any time while using it.
- If you are allergic to dapivirine or any of the other ingredients of this product (listed in section 6).

Warnings and precautions

Talk to your healthcare provider before using the Dapivirine Vaginal Ring.

If you think you may have come into contact with HIV, tell your healthcare provider straight away. More tests may be needed to make sure you are still HIV negative.

It is important to use the Dapivirine Vaginal Ring all the time. Following the instructions on how to correctly use the Dapivirine Vaginal Ring will reduce your chance of becoming HIV-1 infected:

- Always keep the ring in the vagina, especially during vaginal sex and also while you are having your period. Replace the ring each month with a new ring.
- Use the ring all the time, not just when you think you might be at risk of HIV-1 infection.
- If you take the ring out, you are no longer protected from HIV-1 infection.

Overall HIV infection prevention strategy

- Just using the Dapivirine Vaginal Ring may not prevent you from becoming infected with HIV.
- Always practise safer sex to protect yourself from HIV infection.
- Use male or female condoms during sex to reduce contact with semen, vaginal fluids, or blood.
- Do not share personal items, such as razor blades, that can have blood on them.
- Do not share or re-use needles or other tools used for injecting drugs.

- Get tested for other sexually transmitted infections. These infections make it easier for HIV to infect you.

Ask your healthcare provider if you have any more questions about how to prevent getting HIV infected or spreading HIV to other people.

Risk associated with continued use of the ring, when infected

If you continue to use the ring while HIV-1 infected, the HIV-1 virus may undergo changes. These may lead to resistance of the virus and make it more difficult to treat with available anti-HIV treatments. It is important to get tested at least every 3 months for HIV infection.

No protection from HIV-1 infection other than through vaginal sex

The Dapivirine Vaginal Ring only protects against HIV-1 infection during vaginal sex. It does not protect against HIV-1 infection which can happen from any activity other than vaginal sex, such as anal sex, oral sex and exposure to blood or sharp objects that may have been in contact with infected blood.

Use during menstruation

Leave the Dapivirine Vaginal Ring in the vagina during your period.

Contact with vaginal fluids, and blood during your period, may change the colour of the ring during use. Such discolouration is not expected to affect the way the ring works.

Tampons can be used at the same time as the vaginal ring. If using tampons, be careful when removing the tampon, to prevent accidentally pulling out the ring.

Lower levels of the medicine (dapivirine) in the vagina were observed in some women during their period and with tampon use. It is unclear how this lower amount of medicine affects how well the ring works. As mentioned before, additional HIV prevention measures should always be used.

Vaginal practices

A healthy vagina cleans itself. Therefore, you should not use soap or other products to clean the inside of your vagina when using the Dapivirine Vaginal Ring.

You should not use any products to dry out your vagina for sex when using the Dapivirine Vaginal Ring.

These practices may affect how well the ring works to reduce your chance of getting HIV-1 infection.

Pelvic inflammatory disease and sexually transmitted or vaginal infections

The Dapivirine Vaginal Ring does not protect you against vaginal infections or sexually transmitted infections, other than HIV-1 infection. The presence of these commonly occurring infections in your vagina may lead to swelling and pain and cause damage to the lining of your vagina. You may then be at a higher risk of getting HIV infection.

These infections may also spread higher up in your vagina and cause a severe infection of your female organs higher up in your belly (pelvic region). It is important that you seek medical attention and treatment for these infections as soon as possible if you experience any symptoms such as itching, discomfort or pain in the vagina, a discharge from your vagina or severe pain in your lower belly.

Children and adolescents

The Dapivirine Vaginal Ring is not for use in women under 18 years of age.

Using Dapivirine Vaginal Ring when using other medicines

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines or products that need to be put in your vagina.

Ask your healthcare provider before using any of these medicines or products while you are still using the Dapivirine Vaginal Ring.

Pregnancy and breast-feeding

The Dapivirine Vaginal Ring does not prevent pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before using or continuing to use the Dapivirine Vaginal Ring.

Driving and using machines

You can drive or operate machinery as long as you feel well.

3. How to use the Dapivirine Vaginal Ring

Always use the ring exactly as your healthcare provider has told you. Check with your healthcare provider if you are not sure.

Use only one Dapivirine Vaginal Ring and insert it on the same date each month.

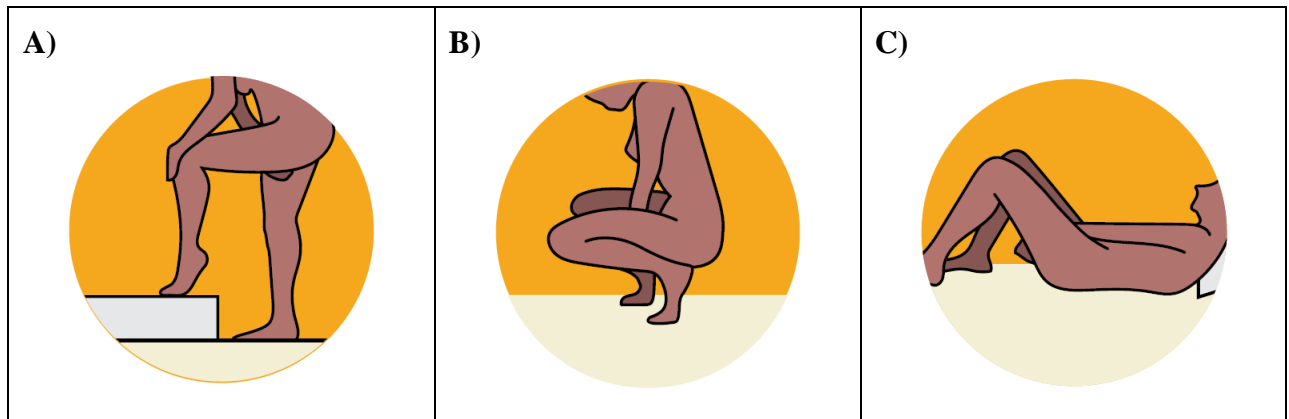
Follow the next steps for insertion of the Dapivirine Vaginal Ring:

Preparation

- Wash your hands in clean water and dry them.
- Remove the Dapivirine Vaginal Ring from the package.

Positioning

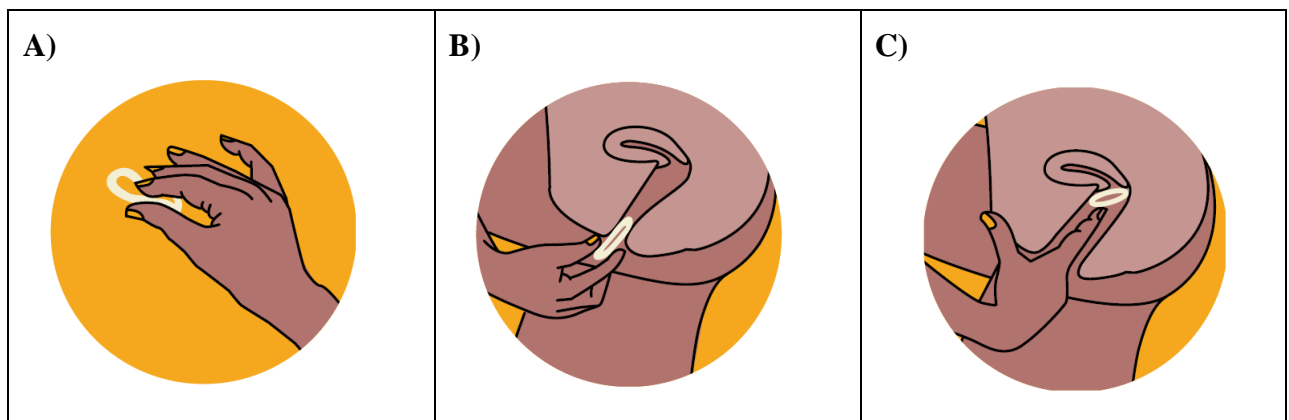
Figure 1: Positioning for Inserting the Dapivirine Vaginal Ring



- Find a comfortable position for insertion of the Dapivirine Vaginal Ring, this could be raising one leg, squatting or lying down (Figure 1A-C).

Insertion

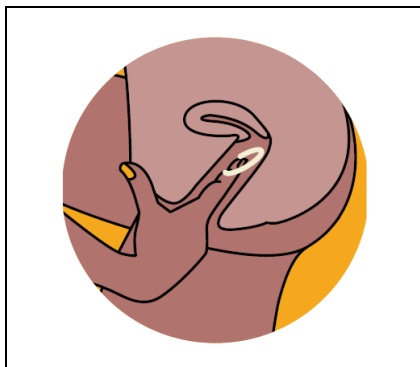
Figure 2: Inserting the Dapivirine Vaginal Ring



- Hold the Dapivirine Vaginal Ring between your thumb and index finger, twisting it into the shape of the number eight (8) or pressing the sides together (Figure 2A).
- Use the other hand to hold the folds of the skin around the vagina open.
- Place the tip of the vaginal ring into the vagina opening (Figure 2B).
- Use the index finger to gently push the folded vaginal ring into the vagina as far as possible (Figure 2C).
- If the ring feels uncomfortable, it may not have been pushed far enough into the vagina. Try again to gently push it into the vagina as far as possible, or remove and reinsert it. Please note: The ring *cannot* be pushed up too far or get lost in the body.
- If it still feels uncomfortable, contact your healthcare provider.
- Wash your hands in clean water and dry them.

Replacement

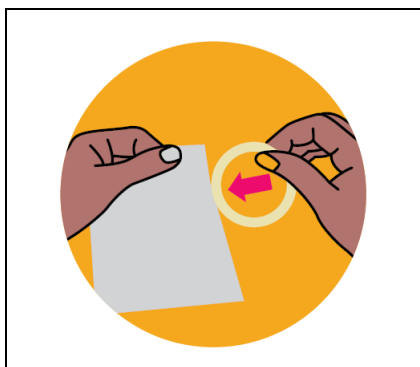
Figure 3: Removing the Dapivirine Vaginal Ring



- Remove the vaginal ring one month from the day it was inserted.
- Wash your hands in clean water and dry them.
- Choose a comfortable position with legs apart.
- Use your finger to hook the vaginal ring and gently pull it out of your vagina (Figure 3).
- Immediately insert a new Dapivirine Vaginal Ring, following the instructions for insertion (Figure 2).

Disposal

Figure 4: Disposing the used Dapivirine Vaginal Ring



- Place the used vaginal ring inside an empty pouch (Figure 4), or wrap it in tissue or toilet paper.
- Dispose the used vaginal ring in the rubbish bin and out of reach of children.
- Do not dispose the vaginal ring in the toilet.
- Wash your hands in clean water and dry them.

If the Dapivirine Vaginal Ring accidentally falls out or is removed

Your Dapivirine Vaginal Ring may accidentally fall out e.g. when you go to the toilet or during vaginal intercourse, or be accidentally removed, e.g. when you remove a tampon.

If this occurs in a place that is not dirty (e.g. in the bed or in the clothes)

- Rinse the Dapivirine Vaginal Ring in clean water.
- Immediately re-insert the Dapivirine Vaginal Ring as described above.

If the Dapivirine Vaginal Ring has touched something dirty (e.g. the toilet):

- Do not re-insert the vaginal ring.
- Discard the vaginal ring as described above.
- Insert a new vaginal ring as described above.

If you use more Dapivirine Vaginal Rings than you should

If you realize you have more than one ring in your vagina, remove all rings and insert a new ring immediately. Do not use any of the rings that you have just removed.

If you keep the ring in the vagina for longer than one month

If you realize that you have kept the ring in the vagina for longer than one month, replace with a new ring immediately.

If you forget to use the Dapivirine Vaginal Ring

Insert a new vaginal ring immediately. Do not insert two rings.

Do not stop using Dapivirine Vaginal Ring

While you are using the Dapivirine Vaginal Ring, to reduce the chance of getting HIV-1 infected, do not stop or interrupt using the ring and do not miss any monthly ring replacements. Stopping the use of the ring, or missing the monthly replacement, may increase your chance of getting HIV-1 infection.

Do not stop using the Dapivirine Vaginal Ring without talking to your healthcare provider

If you have any further questions on the use of the Dapivirine Vaginal Ring, ask your healthcare provider.

If you remove the ring, your chance of getting HIV-1 infection is not reduced.

You must talk to a healthcare provider if you have signs of HIV infection (listed in section 2) when using the Dapivirine Vaginal Ring.

4. Possible side effects

Like all medicines, the Dapivirine Vaginal Ring can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people):

- Urinary tract infection

Common side effects (may affect up to 1 in 10 people):

- Inflammation (swelling, redness and pain) of the vagina and/or the area outside the vagina (vulva),
- Inflammation of the lower part of the womb (cervix),
- Discharge from the vagina,
- Itching of the vagina and/or the area outside the vagina (vulva),
- Pain in the lower part of the belly (abdomen, pelvis),
- Pain or difficulty in passing urine

Uncommon side effects (may affect up to 1 in 100 people):

- Inflammation of the bladder,
- Smell from the vagina,
- Redness or swelling of the lower part of the womb (cervix),

- An uncomfortable feeling of the vagina and/or the area outside the vagina (vulva),
- Pain in the vagina and/or the area outside the vagina (vulva),
- Discharge from the lower part of the womb (cervix),
- Bruising or small spots of internal bleeding of the lower part of the cervix,
- An uncomfortable feeling in the lowest part of the belly (pelvis),
- A sore (ulceration) in the vagina or the lower part of the womb (cervix),
- Passing of urine more often than normally,
- Pain in the bladder,
- Pain in the area below the belly button (navel),
- An uncomfortable feeling at the location where the ring is placed,
- A cut in the vagina

Rare side effects (may affect **up to 1 in 1,000 people**):

- An uncomfortable feeling in the belly,
- An uncomfortable feeling or itching of the genitals,
- An area of the skin which is scraped away in the vulva (vulval abrasion),
- A feeling that you need to pass urine urgently,
- Pain at the location where the ring is placed.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dapivirine Vaginal Ring

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not open the package until the moment you are going to insert the Dapivirine Vaginal Ring.

Do not throw away the Dapivirine Vaginal Ring in the toilet or water drains. Throw the used ring in a rubbish bin out of the reach of children.

6. Contents of the pack and other information

What Dapivirine Vaginal Ring contains:

The active substance in the Dapivirine Vaginal Ring is dapivirine. Each ring contains 25 mg of dapivirine.

The other inactive ingredients are:

Dimeticone, 1,000 centistokes (cSt)

Silicone Elastomer (DDU-4870):

Siloxanes and Silicones, dimethyl, vinyl group-terminated

Platinum(0)-1,3-divinyl-1,1,3,3-tetramethyldisiloxane

Silica, amorphous, fumed, crystalline free

Siloxanes and silicones, dimethyl, methyl vinyl, methyl hydrogen, hydroxyl-terminated

What the Dapivirine Vaginal Ring looks like and the contents of the pack

The Dapivirine Vaginal Ring is a ring that is designed to release a medicine in the vagina. It can easily bend, has an off-white colour and is made of silicone material with an outer diameter of 56 mm and a cross-sectional diameter of approximately 8 mm.

Each Dapivirine Vaginal Ring is packaged into a laminated (PET-Alu/Adhesive/PP), square, heat-sealed pouch. A carton contains either one pouch or three pouches.

Scientific Opinion Holder

International Partnership for Microbicides Belgium (IPM Belgium) AISBL

Square de Meeûs 38/40

1000 Brussels

Belgium

Manufacturer

QPharma AB

Agneslundsvägen 27

Malmö Sweden

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.