PATIENT INFORMATION LEAFLET

INFORMATION FOR THE PATIENT ABOUT

NuvaRing®

SCHEDULING STATUS

S3

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

NuvaRing® Vaginal Ring

Etonogestrel 11,7 mg and ethinylestradiol 2,7 mg

Please read all of this package leaflet carefully before you start using NuvaRing.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- NuvaRing has been prescribed for you personally. Do not share it with other people.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor, or pharmacist.
- Read the leaflet regularly if you are already using NuvaRing. This is important because the information in the leaflet may change.

What is in this leaflet

1. What NuvaRing is and what is it used for
2. What you need to know before you use NuvaRing
3. How to use NuvaRing
4. Possible side effects
5. How to store NuvaRing
6. Contents of the pack and other information

1. What NuvaRing is and what it is used for

NuvaRing is a contraceptive vaginal ring used to prevent pregnancy. Each ring contains a small amount of two female sex hormones: Etonogestrel and ethinylestradiol. The ring slowly releases these hormones into the blood circulation. NuvaRing is considered a low-dose hormonal contraceptive. Since NuvaRing releases two different types of hormones, it is a so-called “combined hormonal contraceptive”.

NuvaRing works like a combined orally taken contraceptive pill (the Pill) but instead of taking a pill every day, the ring is used for 3 weeks in a row. NuvaRing releases two female sex hormones that prevent the release of an egg cell from the ovaries. If no egg cell is released you cannot become pregnant.

2. What you need to know before you use NuvaRing

General notes

In this leaflet, several situations are described where you should stop using NuvaRing, or where NuvaRing may be less reliable. In such situations you should not have intercourse, or you should take extra non-hormonal contraceptive precautions, such as using a male or female condom or other barrier methods. Do **not** use rhythm or temperature methods. These methods can be unreliable because NuvaRing alters the monthly changes of the body temperature and of the cervical mucus.

NuvaRing, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use NuvaRing

Tell your doctor if any of the following conditions applies to you. Your doctor may then advise you to use a different (non-hormonal) method of birth control.

- If you are allergic to ethinylestradiol or etonogestrel, or any of the other inactive substances

of NuvaRing.

- If you have (or have ever had) a blood clot (venous thrombosis) in a blood vessel of your legs, lungs (embolus) or other organs. For possible signs of a blood clot see "**Blood Clots (Thrombosis)**".
- If you have ever had a heart attack, or a stroke, or if you have (or have ever had) a condition that may be a first sign of a heart attack (such as angina pectoris or severe chest pain) or stroke (such as a transient ischaemic attack [a TIA - a slight temporary stroke]).
- If you have a serious risk factor, or several risk factors, for developing a blood clot see also in section "**Blood Clots (Thrombosis)**".
- If you have (or had) a disorder affecting your blood clotting, for instance protein C deficiency.
- If you have (or had) a type of migraine called "migraine with aura".
- If you have diabetes with damaged blood vessels.
- You have (or had) an inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood.
- If you have (or had) severe liver disease and your liver is not yet working normally.
- If you have (or had) a benign or malignant tumour in the liver.
- If you have (or had), or if you may have cancer of the breast or the genital organs.
- If you have any unexplained vaginal bleeding.
- if you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see in section "**Blood clots (Thrombosis)**".
- if you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using NuvaRing, remove the ring immediately and contact your doctor. In the meantime, use non-hormonal contraceptive measures. **For possible signs of a blood clot see in section "Blood Clots (Thrombosis)".**

Do not use NuvaRing if you have hepatitis C and are taking the combination medicine regimen

ombitasvir/paritaprevir/ritonavir with or without dasabuvir (see in section "**Other medicines and NuvaRing**").

Warnings and Precautions

Talk to your doctor before using NuvaRing if any of the following conditions apply to you. Also, if the condition develops or gets worse while you are using NuvaRing you must tell your doctor:

- If you are experiencing mood changes and depressive symptoms or are being treated for depression.
- That you have had depression with previous use of estrogen and/or progesterone/progestogen containing medicines.
- If a close relative has or has ever had breast cancer.
- If you have epilepsy (see in section "**Other medicines and NuvaRing**").
- If you have liver disease (for instance jaundice) or gall bladder disease (for instance gallstones).
- If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- If you have SLE (systemic lupus erythematosus, a disease affecting your natural defence system).
- If you have HUS (hemolytic uremic syndrome, a disorder of blood clotting causing failure of the kidneys).
- if you have sickle cell anaemia (an inherited disease of the red blood cells).
- if you have elevated levels of fat in the blood (hypertriglyceridemia) or a positive family history for this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas) in women using hormonal contraceptives.
- if you have an operation, or if your ability to move around is limited for a long period of time (see in section "**Blood clots (Thrombosis)**").
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using NuvaRing (see in section "**Blood**

clots (Thrombosis)").

- If you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, porphyria [a disease of the blood], herpes gestationis [skin rash with vesicles during pregnancy], Sydenham's chorea [a disease of the nerves in which sudden movements of the body occur], hereditary angioedema [you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing].
- If you have (or have ever had) chloasma (yellowish-brown pigment patches, so called 'pregnancy patches', particularly on the face). If so, avoid too much exposure to the sun or ultraviolet light.
- If you have a medical condition that makes it difficult to use NuvaRing e.g., if you are constipated, have a prolapse of the uterine cervix or have pain during intercourse.
- If you have (or have ever had) an allergic reaction while using NuvaRing, including swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).

Blood Clots (Thrombosis)

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins in the leg, the lung (a lung embolus) or other organs.

Using combined hormonal contraceptive, including NuvaRing, increases a woman's risk of developing such clots (venous thrombosis) compared with a woman not using any combined hormonal contraceptive. The risk of developing a blood clot in a vein is highest during the first year of using a combined hormonal contraceptive for the first time. The risk is also higher if you restart using a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

The risk is not as high as the risk of developing a blood clot during pregnancy. The risk of getting a blood clot with NuvaRing is similar to the risk with contraceptive pills.

It is not yet known how NuvaRing influences the risk of getting a blood clot compared with contraceptive pills.

If you use a combined hormonal contraceptive your risk of a blood clot in a vein increases further:

- the older you are
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age
- if you are overweight
- if you must have an operation, or if your ability to move around is limited for a long period of time because of an injury or illness, or you have your leg in a plaster cast.
  If this applies to you, it is important to tell your doctor that you are using NuvaRing, as the treatment may have to be stopped. Your doctor may tell you to stop using your hormonal contraception several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using NuvaRing again after you are able to move around.
  See also section "**Do not use NuvaRing**".
- if you gave birth less than a few weeks ago.

Blood clots in an artery

A blood clot in an artery can cause serious problems e.g., a blood clot in an artery in the heart causes a heart attack, or in the brain causes a stroke.

The use of a combined hormonal contraceptive has been connected with an increased risk of clots in the arteries. This risk increases further:

- the older you are
- **if you smoke. When using a combined hormonal contraceptive like NuvaRing you are strongly advised to stop smoking, especially if you are older than about 35 years.**
- if you are obese (body mass index > 30 kg/m^2)
- if you have high blood pressure. If you develop high blood pressure while using NuvaRing, you may be told to stop using it.
- if a close relative has had a heart attack or stroke at a young age
- if you have a high level of fat in your blood (cholesterol or triglycerides)
- if you have diabetes
- if you get migraine
- if you have a problem with your heart (e.g., valve disorder, disturbance of the rhythm).

Symptoms of blood clots

Remove NuvaRing and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- unusual pain and/or swelling in one of your legs
- severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of your body.

Following a blood clot, recovery is not always complete. Very occasionally serious permanent disabilities may occur or the blood clot may even be fatal.

Cancer

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptives, such as NuvaRing.

In studies with the combined pill, breast cancer has been found slightly more often in women using combined pills, but it is not known whether this is caused by the treatment e.g., it may be that tumours are found more in women on combined pills because they are examined by the doctor more often. The increased occurrence of breast cancer becomes gradually less after stopping the combined pill so that 10 years after stopping, the extra risk has gone.

In the additional study that included both oral and non-oral hormonal contraceptives, such as NuvaRing, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who had never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100 000 women-years.

It is important to regularly check your breasts and you should contact your doctor if you feel any lump. You should also tell your doctor if a close relative has, or ever had breast cancer. (See section “**Warnings and precautions**”).

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain. Chronic infection with the Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer.

For users of the combined pill, it has been reported that cancer of the endometrium (the lining of the womb) and cancer of the ovaries occur less frequently. This may also be the case for

NuvaRing but this has not been confirmed.

Other medicines and NuvaRing

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Some medicines may cause particular problems when you are using combined hormonal contraceptives, such as NuvaRing.

- There are medicines that can make NuvaRing less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used to treat:
  - epilepsy (e.g., primidone, phenytoin, phenobarbitone, carbamazepine, oxcarbamazepine, topiramate, felbamate)
  - tuberculosis (e.g., rifampicin)
  - HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
  - Hepatitis C virus infection (e.g., boceprevir, telaprevir)
  - other infectious diseases e.g., griseofulvin
  - high blood pressure in the blood vessels of the lungs (bosentan).
- The herbal product *St. John's wort* may also stop NuvaRing from working properly. If you want to use herbal products containing *St. John's wort* while you are already using NuvaRing you should consult your doctor first.
- NuvaRing may also interfere with the working of other medicines, such as ciclosporin and the anti-epileptic lamotrigine.
- Do not use NuvaRing if you have Hepatitis C and are taking the combination medicine regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). NuvaRing can be restarted approximately 2 weeks after completion of treatment with the combination medicine regimen (see section "**Do not use NuvaRing**").
- If you are taking medicines or herbal products that might make NuvaRing less effective, a

barrier contraceptive method should also be used. Since the effect of another medicine on NuvaRing may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Note: Do not use NuvaRing with a diaphragm, cervical cap, or a female condom.

You can use tampons while using NuvaRing. Insert NuvaRing before inserting a tampon. You should be careful when removing a tampon to be sure that the ring is not accidentally pulled out. If the ring does come out, simply rinse the ring in cool to lukewarm (do not use hot water) water and immediately reinsert it.

Ring breakage has occurred when also using a vaginal product such as a lubricant or treatment for infection (see section "**What to do if, Your ring breaks**"). Using spermicides or vaginal yeast products will not reduce the contraceptive efficacy of NuvaRing.

Use of NuvaRing in pregnancy and breastfeeding

NuvaRing must not be used by women who are pregnant, or who think they may be pregnant. If you get pregnant, please consult your doctor, pharmacist or other healthcare professional for advice before using NuvaRing.

NuvaRing is not usually recommended for use during breastfeeding. If you wish to use NuvaRing while breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

NuvaRing is unlikely to affect your ability to drive or use machines.

Laboratory tests

If you are having any blood or urinary test, tell your healthcare professional that you are using

NuvaRing as it may affect the results of some tests.

3. How to use NuvaRing

You can insert and remove NuvaRing yourself. Your doctor will tell you when to start using NuvaRing for the first time. The vaginal ring must be inserted on the correct day in your monthly cycle (see section "**When to start with the first ring**") and left in place for 3 consecutive weeks. Regularly check that NuvaRing is in your vagina (for example, before and after intercourse) to ensure that you are protected from pregnancy. After the 3rd week, you take NuvaRing out and have a one-week break. You will usually have your monthly period during this ring-free interval.

While using NuvaRing, you should not use certain female barrier contraceptive methods such as a vaginal diaphragm, cervical cap, or female condom as your back-up method of birth control because NuvaRing may interfere with the correct placement and position of a diaphragm, cervical cap, or female condom.

How to insert and remove NuvaRing

1. Before inserting the ring, check that it is not out of date (see section "**5**. **How to store NuvaRing**").
2. Wash your hands before inserting or removing the ring.
3. Choose the position for inserting that is most comfortable to you, like standing with one leg up, squatting, or lying down.
4. Remove NuvaRing from its sachet.
5. Hold the ring between your thumb and index finger, press the opposite sides together and insert the ring into the vagina (see Figures 1 to 4). When NuvaRing is in place you should not feel anything. If you feel uncomfortable, gently change the position of the NuvaRing (e.g., push the ring a bit further into the vagina) until it is comfortable. The exact position of the ring inside the vagina is not important.
6. After 3 weeks remove NuvaRing from the vagina. You can do this by hooking your index

finger under the front rim of the ring or by grasping the rim and pulling it out (see Figure 5).

7. Dispose of the used ring with the normal household waste, preferably inside the reclosable sachet. Do not flush NuvaRing down the toilet.

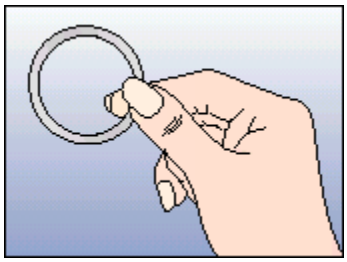


Figure 1

Take NuvaRing out of the sachet

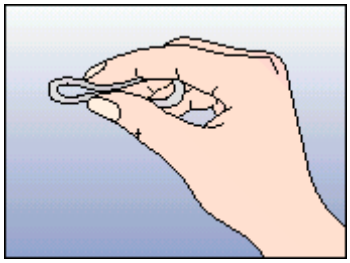


Figure 2

Compress the ring

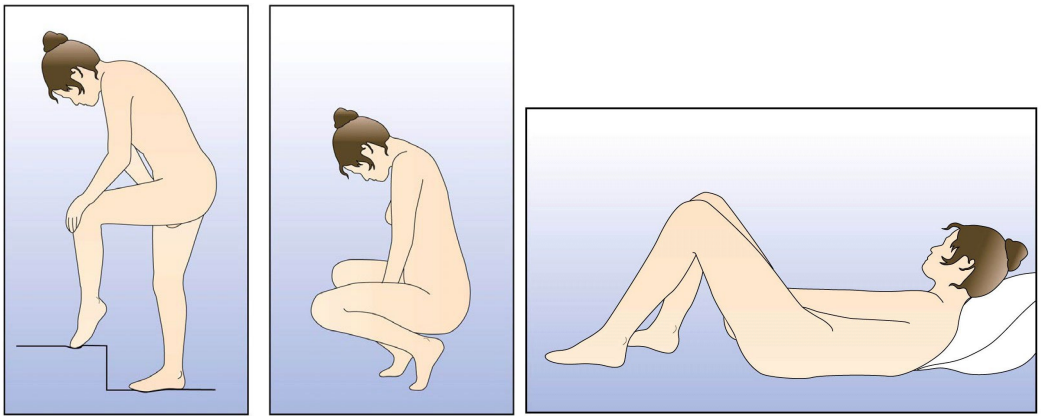


Figure 3

Choose a comfortable position to insert the ring

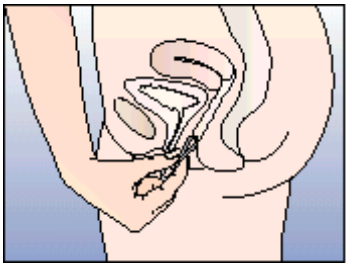


Figure 4A

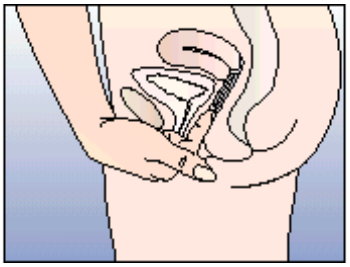


Figure 4B

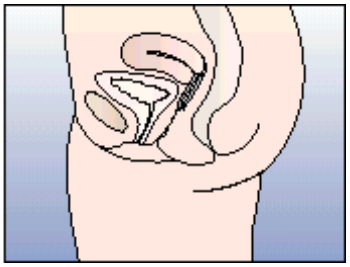


Figure 4C

Insert the ring into the vagina with one hand (Figure 4A), if necessary the labia may be spread with the other. Push the ring into the vagina until the ring feels comfortable (Figure 4B). Leave the ring in place for 3 weeks (Figure 4C).

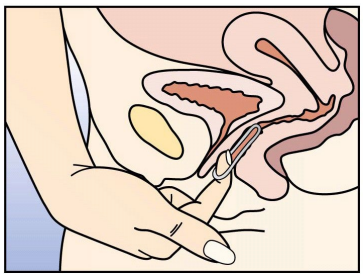


Figure 5

NuvaRing can be removed by hooking the index finger under the ring or by grasping the ring between the index and middle finger and pulling it out.

Three weeks in, one week out

1. Starting with the day you put it in, the vaginal ring must be left in place **without interruption** for 3 weeks.
2. After 3 weeks you remove the ring on the same day of the week and at approximately the same time as it was put in. For example, if you put NuvaRing in on a Wednesday at about 22:00 h, you should remove the ring 3 weeks later, on Wednesday, at about 22:00 h.
3. After you have removed the ring, you do not use a ring for 1 week. During this week a

vaginal bleed should occur. Usually this starts 2 to 3 days after removal of NuvaRing.

4. Start a new ring exactly after the one week interval (again on the same day of the week and approximately the same time), even if you have not stopped bleeding. If the new ring is inserted more than 3 hours too late, the protection from pregnancy may be reduced. Follow the instructions in section "**What to do if, You have forgotten to insert a new ring after the ring-free interval**".

If you use NuvaRing as described above, your vaginal bleed will take place every month on roughly the same days.

When to start with the first ring

- **You have not used a hormonal contraceptive during the last month**

Insert the first NuvaRing on the first day of your natural cycle (i.e., the first day of your menstrual period). You don't need to use or take any other precautions to prevent pregnancy. You can also start NuvaRing between day 2 and day 5 of your cycle, but if you have sexual intercourse during the first 7 days of NuvaRing use make sure that you also use an additional contraceptive method (such as a male condom). You only have to follow this advice when you use NuvaRing for the first time.

- **You have used a combined Pill during the last month**

Start using NuvaRing at the latest the day following the tablet-free period of your present Pill. If your Pill pack also contains inactive tablets, start NuvaRing at the latest on the day after the last inactive tablet. If you are not sure which tablet this is, ask your doctor or pharmacist. Never extend the hormone-free interval of your current Pill pack beyond its recommended length.
If you have used the Pill consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill on any day of your current Pill pack and start using NuvaRing immediately.

- **You have used a transdermal patch during the last month**

Start using NuvaRing at the latest the day following your usual patch-free break. Never

extend the patch-free break beyond its recommended length.

If you have used the patch consistently and correctly and if you are sure that you are not pregnant, you can also stop using the patch on any day and start using NuvaRing immediately.

- **You have used a minipill (progestogen-only pill) during the last month**

You can stop taking the minipill any day and start NuvaRing the next day, at the same time you would normally have taken your pill. But make sure you also use an additional contraceptive method (such as a male condom) for the first 7 days of ring use.

- **You have used an injectable or implant or a progestogen-releasing Intrauterine device (IUD) during the last month**

Start using NuvaRing when your next injection is due or on the day that your implant or your progestogen-releasing IUD is removed. But make sure you also use an additional contraceptive method (such as a male condom) for the first 7 days of ring use.

- **After having a baby**

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start using NuvaRing. Sometimes it is possible to start sooner. Your doctor will advise you.

If you are breastfeeding and want to use NuvaRing, you should discuss this first with your doctor.

- **After a miscarriage or an abortion**

Your doctor will advise you.

What to do if

Your ring is accidentally expelled from the vagina

NuvaRing may accidentally be expelled from the vagina, e.g., if it has not been inserted properly, while removing a tampon, during sexual intercourse, during constipation, or if you have a prolapse of the womb. Therefore, it is good habit to regularly check whether the ring is still in your vagina (for example, before and after intercourse).

Your ring has temporarily been out of the vagina

NuvaRing might still protect you from getting pregnant depending on how long it has been out of your vagina.

If the ring has been out of your vagina for:

- **Less than 3 hours**, it will still protect you from pregnancy. You should rinse the ring with cold to lukewarm water (do not use hot water) and put the ring back in as soon as possible but only if the ring has been out of the vagina for less than 3 hours.
- **More than 3 hours during the 1st and 2nd week**, it may not protect you from pregnancy. You should rinse the ring with cold to lukewarm water (do not use hot water) and put the ring back in the vagina as soon as you remember and leave the ring in place without interruption for at least 7 days. Use a male condom if you have sexual intercourse during these 7 days. If you are in your 1st week, and you had sexual intercourse during the past 7 days, there is a possibility you may be pregnant. In that case contact your doctor.
- **More than 3 hours in the 3rd week** it may not protect you from pregnancy. You should discard that ring and choose between one of the following two options:
    1. Insert a new ring immediately.

       This will start the next three-week use period. You may not have your period, but breakthrough bleeding and spotting may occur.
    2. Do not insert the ring again. Have your period first and insert a new ring no later than 7 days from the time the previous ring was removed or fell out. You should only choose this option if you have used NuvaRing continuously during the previous 7 days.
- **unknown amount of time,** you may not be protected from pregnancy. Perform a pregnancy test and consult your doctor prior to inserting a new ring.

Your ring breaks

Very rarely NuvaRing may break. A broken ring is unlikely to cause an overdose because the

ring will not release a higher dose of contraceptive hormones. Vaginal injury associated with ring breakage has been reported.

If NuvaRing breaks, expulsion of the ring is likely to occur (see section "**What to do if, Your ring has temporarily been out of the vagina**"). Therefore, if you notice that your NuvaRing has broken, discard that ring and replace it with a new ring as soon as possible. Use extra contraceptive precautions (e.g., a male condom) during the next 7 days. If you had sexual intercourse before you noticed the ring breakage, please contact your doctor.

You have inserted more than one ring

There have been no reports of serious harmful effects due to an overdose of the hormones in NuvaRing. If you have accidentally inserted more than one ring, you may feel sick (nausea), or have vomiting or vaginal bleeding. Remove excess rings and contact your doctor if these symptoms persist.

You have forgotten to insert a new ring after the ring-free interval

If your **ring-free interval** was **longer than 7 days**, put a new ring as soon as you remember. Use extra contraceptive precautions (such as a male condom) if you have sexual intercourse during the next 7 days. If you had sexual intercourse in the ring-free interval, there is a possibility you may be pregnant. In that case contact your doctor immediately. The longer the ring-free interval, the higher the risk you have become pregnant.

You have forgotten to remove the ring

- If your ring has been left in place for between **3 and 4 weeks**, it will still protect you from pregnancy. Have your regular ring-free interval of one week and subsequently insert a new ring.
- If your ring has been left in place for **more than 4 weeks** there is a possibility of becoming pregnant. Contact your doctor before you start with a new ring.

You have missed a menstrual period

- **You have followed the instructions for NuvaRing**

If you have missed a menstrual period but you followed the instructions for NuvaRing, and have not used other medicines, it is very unlikely that you are pregnant. Continue to use NuvaRing as usual. If you miss your menstrual period twice in a row however, you may be pregnant. Tell your doctor immediately. Do not start the next NuvaRing until your doctor has checked you are not pregnant.

- **If you have not followed the instructions for NuvaRing**

If you have missed a menstrual period and you did not follow the instructions, and you do not have your expected period in the first normal ring-free interval, you may be pregnant. Contact your doctor before you start with a new NuvaRing.

You have unexpected bleeding

While using NuvaRing, some women have unexpected vaginal bleeding between menstrual periods. You may need to use sanitary protection. In any case, leave the ring in the vagina and continue to use the ring as normal. If the irregular bleeding continues, becomes heavy or starts again, tell your doctor.

You want to change the first day of your menstrual period

If you follow the instructions for NuvaRing, your menstrual period (withdrawal bleed) will begin in the ring-free interval. If you want to change the day it starts, you can make the ring-free interval shorter (but never longer!). For example, if your period usually begins on a Friday, you can change this to a Tuesday (3 days earlier) from next month onwards. Simply insert your next ring 3 days earlier than usual.

If you make your ring-free interval very short (e.g., 3 days or less) you may not have your usual bleeding. You may have spotting (drops or flecks of blood) or breakthrough bleeding while

using the next ring.

If you are not sure how to proceed, contact your doctor for advice.

You want to delay your menstrual period

Although it is not the recommended regimen, delay of your menstrual period (withdrawal bleed) is possible by inserting a new ring immediately after removing the current ring, with no ring-free interval between rings. You can leave the new ring inserted for up to a maximum of 3 weeks. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this new ring. When you want your period to begin, just remove the ring. Have your regular ring-free interval of one week and subsequently insert a new ring.

You can ask your doctor for advice before deciding to delay your menstrual period.

You want to stop using NuvaRing

You can stop using NuvaRing any time you want.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop using NuvaRing because you want to get pregnant, you should wait until you have had a natural period before trying to conceive. This helps you calculate when the baby will be due.

Contact your doctor as soon as possible if:

- You notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also in section "**Do not use NuvaRing**" and section "**Warnings and precautions**").
- Your ability to move around is limited for a long period of time or you are to have surgery. Tell your doctor at least four weeks in advance (see also in section "**Blood clots (Thrombosis)**").
- You feel a lump in your breast. This symptom may indicate breast cancer (see also in

section “**Cancer**”).

- You experience an allergic reaction, including hives, swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).
- You have severe pain in your abdomen.
- You have unusual, heavy vaginal bleeding. This symptom may indicate cervical cancer.
- You are going to use other medicines (see also in section “**Other medicines and NuvaRing**”).
- The ring was out of the vagina for longer than 3 hours in the **first week** of use and you had intercourse in the 7 days before.
- You have forgotten to insert a new ring after the ring-free interval of 7 days.
- You left NuvaRing in place for more than 4 weeks. Do not start the next ring until your doctor tells you.
- You missed your period twice in a row or suspect you are pregnant. Do not start the next ring until your doctor tells you.
- You have an urgent, frequent, burning, and/or painful urination, and cannot locate the ring in the vagina. These symptoms may indicate accidental placement of NuvaRing into the urinary bladder.
- If you locate the ring in your vagina, but are unable to remove it.

Remove NuvaRing and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described in section “Blood clots (Thrombosis)”.

4. Possible side effects

NuvaRing can cause side effects, although not everybody gets them.

Serious reactions seen with NuvaRing, as well as the related symptoms, are described in “Blood Clots (Thrombosis)” and “Cancer”.

Users of NuvaRing have reported the following side effects:

Common side effects (affecting more than 1 in 100, but less than 1 in 10 women)

- abdominal pain, feeling sick (nausea)
- yeast infection of the vagina (such as “thrush”), discomfort in the vagina due to the ring, genital itching, secretion from the vagina
- headache or migraine, depressive moods, lower sex drive
- breast pain, painful menstrual periods
- acne
- weight gain
- the ring falling out.

Uncommon side effects (affecting more than 1 in 1 000, but less than 1 in 100 women)

- disturbed vision, dizziness
- swollen abdomen, vomiting, diarrhoea or constipation
- feeling tired, unwell or irritable, mood changes, mood swings
- extra fluid in the body (oedema)
- bladder or urinary tract infection
- difficulty or pain when passing urine, strong desire or need to pass urine, passing urine more often
- problems during intercourse, including pain, bleeding or partner feeling the ring
- increased blood pressure
- increased appetite
- back pain, muscle spasms, pain in legs or arms
- less sensitive skin
- sore or larger breasts, fibrocystic breast disease (cysts in the breasts which may become swollen or painful)
- inflammation of the cervix, cervical polyps (growths in the cervix), rolling outward of the margin of the cervix (ectropion)

- genital secretion, changes to menstrual periods (e.g., periods can be heavy, long, irregular or stop altogether), pelvic discomfort, premenstrual syndrome, spasm of the uterus
- vaginal infection (fungal and bacterial), burning feeling, smell, pain, discomfort or dryness in the vagina or vulva
- hair loss, eczema, itching, rash or hot flushes
- ring breakage.

Rare side effects (affecting more than 1 in 10 000, but less than 1 in 1 000 women)

- blood clot in a vein
- blood clot in an artery

The following rare side effects have been reported during market use of NuvaRing: allergic reactions (hypersensitivity), including hives, swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis); vaginal injury associated with ring breakage; breast discharge, penis discomfort of the partner (such as irritation, rash, itching).

Not all side effects reported for NuvaRing are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NuvaRing, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of NuvaRing.

5. How to store NuvaRing

Store NuvaRing in the original package.

Prior to dispensing: Refrigerate at 2 to 8 °C for up to 36 months.

At the time of dispensing: The dispenser places a date of dispensing on the box. The product should not be inserted after the expiry date or 4 months from the date of dispensing, whichever comes first.

After dispensing: Store at room temperature below 30 °C for up to 4 months.

See "**3. How to use NuvaRing**". The dispenser has to indicate on the box the date of dispensing and the date before which NuvaRing has to be used. After removal, NuvaRing should be stored in the reclosable sachet. NuvaRing should be disposed of with the normal household waste in a manner that avoids accidental contact with other people. NuvaRing should not be flushed down the toilet.

Keep out of reach of children.

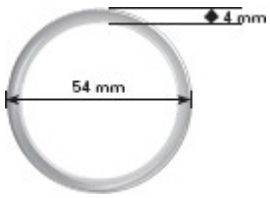
6. Contents of the pack and other information

What NuvaRing contains

The active substances are: Etonogestrel 11,7 mg and ethinylestradiol 2,7 mg.

The other inactive substances are: Ethylene vinyl acetate copolymer, 28 % vinyl acetate; ethylene vinyl acetate copolymer, 9 % vinyl acetate and magnesium stearate.

What NuvaRing looks like and contents of the pack



NuvaRing is a smooth, transparent ring without major visible damages, with one transparent to less transparent region. The ring has an outer diameter of 54 mm and a cross-sectional

diameter of 4 mm.

NuvaRing contraceptive vaginal ring is ready-for-use, packed in a sealed reclosable sachet of laminated aluminium foil with a low-density polyethylene heat seal coating on the inside in contact with the vaginal ring, and a non-sealable polyethyleneterephthalate layer on the outside. The sachet incorporates a low-density polyethylene reclosable feature (zipper) so that after use the ring can be put back into it, for hygienic disposal. The sachet is placed into a flat carton box. Each box contains 1 ring.

Holder of certificate of registration

Organon South Africa (Pty) Ltd

Spaces, 1st Floor, 22 Magwa Crescent, Gateway West

Waterfall City, Midrand, 2090

South Africa

Tel. No.: 087 106 9655

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