

Package leaflet: information for the user

NuvaRing 0.120 mg/0.015 mg per 24 hours, vaginal delivery system
etonogestrel/ethinylestradiol

Important things to know about combined hormonal contraceptives:

These are one of the most reliable reversible contraceptive methods when used correctly.

They slightly increase the risk of developing a blood clot (thrombosis) in the veins and arteries, especially in the first year of using a combined hormonal contraceptive or if you restart after a break of 4 weeks or more.

Pay close attention and contact your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots (thrombosis)').

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it is prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Contact your doctor or pharmacist.

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1. What is NuvaRing and what is it used for?

NuvaRing is a contraceptive for vaginal use. Each ring contains a small amount of two female sex hormones – etonogestrel and ethinylestradiol. These hormones are slowly released into the blood by the ring. Due to the small amount of hormones released, NuvaRing is considered a low-dose hormonal contraceptive. Because NuvaRing releases two different hormones, it is called a combined hormonal contraceptive.

NuvaRing works in the same way as the combined contraceptive pill (the pill) but instead of taking a pill every day, the ring is used continuously for 3 weeks. NuvaRing releases two female sex hormones that prevent an egg from being released from the ovaries. If no egg is released, you cannot become pregnant.

2. When should you not use this medicine or be extra careful?

General remarks

Before you start using NuvaRing, read the information about blood clots (thrombosis) in section 2. It is especially important that you read about the symptoms of a blood clot – see section 2 'Blood clots (thrombosis)'.

This leaflet describes various situations in which you should stop using NuvaRing or where the reliability of NuvaRing may be reduced. You should not have sexual intercourse or you should use an additional non-hormonal contraceptive. In general, a male condom or another barrier method is suitable. Do not use the calendar or temperature method. These can be unreliable because NuvaRing affects the monthly changes in body temperature and cervical mucus.

Like other hormonal contraceptives, NuvaRing does not protect against infection with the HIV virus (AIDS) or other sexually transmitted diseases.

When should you not use this medicine?

You should not use this medicine if you have any of the conditions listed below. If you have one or more of the conditions listed below, tell your doctor. Your doctor will discuss with you which other form of contraception is more suitable for you.

You have a blood clot in a blood vessel of the legs (deep vein thrombosis, DVT), the lungs (pulmonary embolism, PE), or another organ, or you have had this in the past.

You know you have a disorder that affects your blood clotting – for example, protein C deficiency, protein S deficiency, antithrombin-III deficiency, factor V Leiden, or antibodies against phospholipids.

You need to have surgery or you are not able to move around for a long time (see section 'Blood clots (thrombosis)').

You have ever had a heart attack or a stroke.

You have angina pectoris (a condition that causes severe chest pain and can be a first sign of a heart attack) or a transient ischemic attack (TIA – temporary symptoms of a stroke), or you have ever had this.

You have one of the following diseases, which can increase the risk of a blood clot in your arteries:

- severe diabetes with damage to blood vessels
- severely elevated blood pressure
- a severely increased fat content in your blood (cholesterol or triglycerides)
- a condition called hyperhomocysteinemia.

You have a type of migraine called 'migraine with aura', or you have had this.

You have an inflammation of the pancreas (pancreatitis) or have ever had this where the level of certain fats in your blood is/was too high.

You have a severe liver disease or have ever had this and your liver is not yet functioning completely well.

You have a benign or malignant tumor in the liver or have ever had this.

You may have breast cancer or cancer of the genital organs or have ever had this.

You have unusual vaginal bleeding, the cause of which has (yet) to be determined.

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

If any of the mentioned situations occur while you are using NuvaRing, remove NuvaRing immediately and contact your doctor. In the meantime, use another non-hormonal contraceptive.

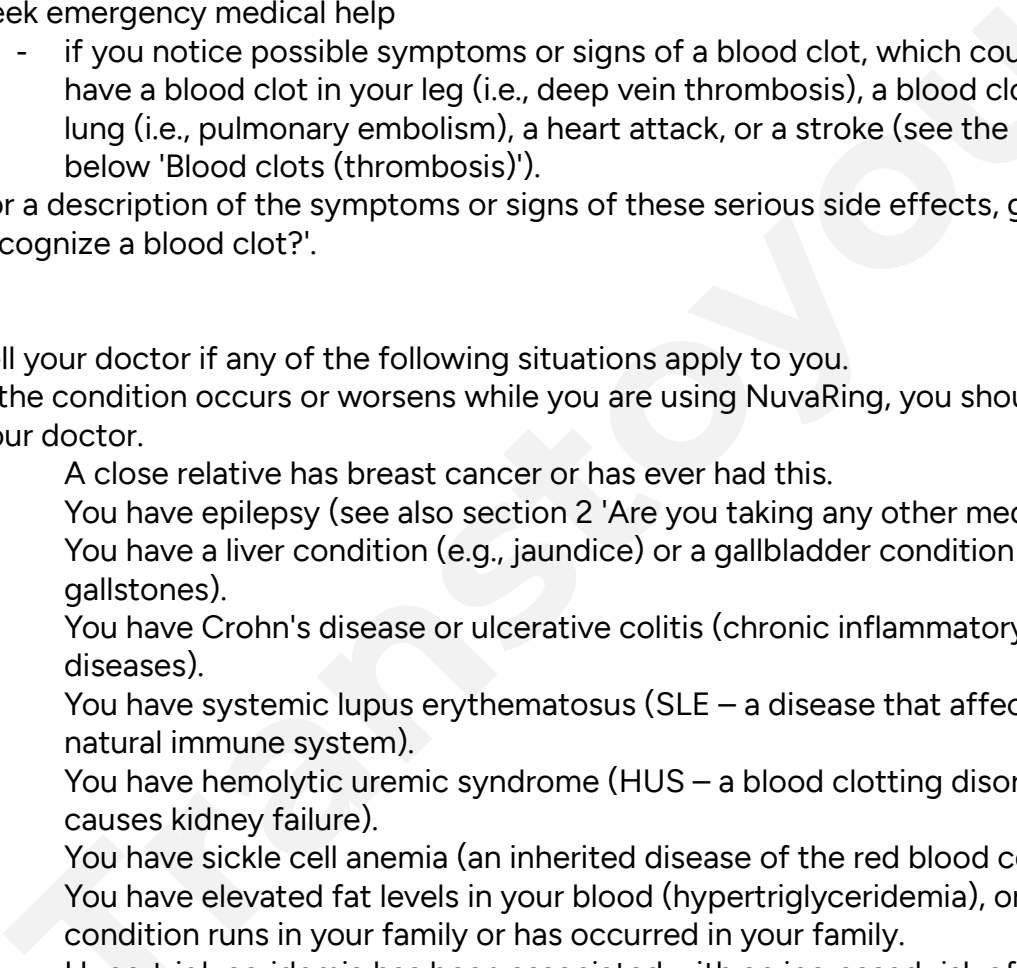
Do not use NuvaRing if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir (see section 2 'Are you taking any other medicines?').

When should you be extra careful with this medicine?

When should you contact your doctor?

Seek emergency medical help

- if you notice possible symptoms or signs of a blood clot, which could mean you have a blood clot in your leg (i.e., deep vein thrombosis), a blood clot in your lung (i.e., pulmonary embolism), a heart attack, or a stroke (see the section below 'Blood clots (thrombosis)').

For a description of the symptoms or signs of these serious side effects, go to 'How to recognize a blood clot?'.


Tell your doctor if any of the following situations apply to you.

If the condition occurs or worsens while you are using NuvaRing, you should also tell your doctor.

A close relative has breast cancer or has ever had this.

You have epilepsy (see also section 2 'Are you taking any other medicines?').

You have a liver condition (e.g., jaundice) or a gallbladder condition (e.g., gallstones).

You have Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases).

You have systemic lupus erythematosus (SLE – a disease that affects your natural immune system).

You have hemolytic uremic syndrome (HUS – a blood clotting disorder that causes kidney failure).

You have sickle cell anemia (an inherited disease of the red blood cells).

You have elevated fat levels in your blood (hypertriglyceridemia), or this condition runs in your family or has occurred in your family.

Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).

You need to undergo surgery or you are immobile for a long period (see 'Blood clots (thrombosis)' in section 2).

If you have recently given birth, you have an increased risk of developing blood clots. Ask your doctor how soon after delivery you can start using NuvaRing.

You have inflammation in the veins just under the skin (superficial thrombophlebitis).

You have varicose veins.

You have a condition that first appeared or worsened during pregnancy or previous use of sex hormones (e.g., hearing loss, porphyria [a blood disorder], herpes gestationis [a rash with blisters during pregnancy], or Sydenham's chorea [a nervous disorder with sudden body movements]).

You experience symptoms of angioedema such as swelling of your face, tongue, and/or throat and/or difficulty swallowing or hives possibly with breathing problems. In this case, contact your doctor immediately. Products containing estrogens can cause or worsen symptoms of hereditary and acquired angioedema.

You have chloasma (yellow-brown pigment spots, so-called 'pregnancy spots', especially on the face) or have had it before. If this is the case, it is advisable to avoid excessive exposure to sunlight or ultraviolet light.

You have a condition that makes the use of NuvaRing difficult, for example, you suffer from bowel obstruction, uterine prolapse, or pain during intercourse.

You need to urinate frequently, urgently, with a burning and/or painful sensation, and you cannot find the ring in the vagina. These symptoms may indicate that NuvaRing has accidentally been placed in the bladder.

BLOOD CLOTS (THROMBOSIS)

If you use a combined hormonal contraceptive like NuvaRing, you have a higher risk of developing blood clots than if you do not use a combined hormonal contraceptive. In rare cases, a blood clot can block a blood vessel and cause serious problems.

Blood clots can occur

in veins (this is called 'venous thrombosis', 'venous thromboembolism', or VTE)

in arteries (this is called 'arterial thrombosis', 'arterial thromboembolism', or ATE).

People do not always fully recover from blood clots. In rare cases, there can be long-term serious effects, or in very rare cases, blood clots can be fatal.

It is important for you to know that the overall risk of a harmful blood clot from NuvaRing is small.

HOW TO RECOGNIZE A BLOOD CLOT?

Seek emergency medical help if you notice any of the following complaints or symptoms.

Do you experience any of these complaints or symptoms?

swelling of a leg or along a vein in a leg or foot, especially if accompanied by:

- o pain or tenderness in the leg, which you may only feel when standing or walking
- o increased temperature in the affected leg
- o change in the color of the skin of the leg, for example, becoming pale, red, or blue

sudden unexplained shortness of breath or rapid breathing

What might you suffer from?

Deep vein thrombosis

Pulmonary embolism

sudden cough without an obvious cause, which may produce blood
sharp chest pain, which may become worse when you take a deep breath
severe light-headedness or dizziness
rapid or irregular heartbeat
severe pain in your stomach

If in doubt, contact a doctor, as some of these symptoms, such as coughing or shortness of breath, may mistakenly be considered a milder condition, such as a respiratory infection (e.g., a cold).

Symptoms usually occur in one eye:

sudden loss of vision, or
painless blurred vision, which may develop into loss of vision

Retinal vein thrombosis (blood clot in the eye)

pain, discomfort, pressure or heaviness in the chest
tight or full feeling in the chest, arm or below the breastbone
full feeling, indigestion or shortness of breath
discomfort in the upper body radiating to the back, jaw, throat, arm and stomach
sweating, nausea, vomiting or dizziness
extreme weakness, anxiety or shortness of breath
rapid or irregular heartbeat

Heart attack

sudden weakness or numbness of the face, arm or leg, especially on one side of the body
sudden confusion, trouble speaking or understanding
sudden trouble seeing in one or both eyes
sudden trouble walking, dizziness, loss of balance or coordination
sudden, severe or prolonged headache with no known cause
decreased consciousness or fainting with or without seizure

Stroke

The symptoms of a stroke may sometimes be brief and recover almost immediately and completely. However, you should still seek

emergency medical help, as you may be at risk of having another stroke.

swelling and slight bluish
discoloration of an arm or leg
severe pain in your abdomen (acute
abdomen)

Blood clots
blocking other
blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

The use of combined hormonal contraceptives has been associated with a higher risk of blood clots in a vein (venous thrombosis). However, these side effects are rare. They usually occur in the first year of using a combined hormonal contraceptive.

If a blood clot forms in a vein in a leg or foot, it can cause a deep vein thrombosis (DVT).

If a blood clot is carried from the leg and lodges in the lung, it can cause a pulmonary embolism.

It is very rare for a blood clot to form in a vein in another organ, such as the eye (retinal vein thrombosis).

When is the risk of forming a blood clot in a vein highest?

The risk of getting a blood clot in a vein is highest in the first year a woman first uses a combined hormonal contraceptive. The risk may also be increased if you restart using a combined hormonal contraceptive (the same product, or a different product than before) after a break of 4 weeks or more.

After the first year, the risk decreases, but it remains slightly higher than if you were not using a combined hormonal contraceptive.

If you stop using NuvaRing, your risk of a blood clot returns to normal within a few weeks.

How high is the risk of a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you use.

The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism) with NuvaRing is small.

Out of every 10,000 women who do not use any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year. Out of every 10,000 women who use a combined hormonal contraceptive containing levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot in a year.

Out of every 10,000 women who use a combined hormonal contraceptive containing norelgestromin or etonorgestrel (such as NuvaRing), about 6-12 will develop a blood clot in a year.

The risk of developing a blood clot depends on your personal medical history (see section 'Factors that increase your risk of a blood clot in a vein/artery' below).

Women who do not use a combined hormonal pill/patch/ring and are not pregnant	Risk of developing a blood clot in a year About 2 out of every 10,000 women
Women who use a combination pill containing levonorgestrel, norethisterone, or norgestimate	About 5-7 out of every 10,000 women
Women who use NuvaRing	About 6-12 out of every 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with NuvaRing is small, but there are certain conditions that increase the risk. Your risk is higher:

if you are severely overweight (BMI [body mass index] over 30 kg/m²)

if one of your close relatives has had a blood clot in a leg, lung, or other organ at a young age (e.g., before the age of 50). In that case, you may have a hereditary clotting disorder.

if you need to undergo surgery or if you are not able to move around for a long time due to an injury or illness, or if your leg is in a cast.

It may be necessary to stop using NuvaRing several weeks before surgery, or when you are less mobile. If you need to stop using NuvaRing, ask your doctor when you can start using it again.

if you are getting older (particularly over the age of 35) It may be necessary to stop using NuvaRing a few weeks before surgery or when you are less mobile. If you need to stop using NuvaRing, ask your doctor when you can start using it again.

as you get older (particularly around over 35 years)

if you have given birth in the past few weeks.

The risk of a blood clot increases as more of these conditions apply to you.

A plane trip (longer than 4 hours) can temporarily increase your risk of a blood clot, especially if some of the other mentioned conditions apply to you. It is important that you tell your doctor if one or more of these conditions apply to you, even if you are unsure. Your doctor may decide that you should stop using NuvaRing.

If any of the above conditions change while you are using NuvaRing, for example, if a close relative has a blood clot (thrombosis) with no known cause, or if you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Just like a blood clot in a vein, a blood clot in an artery can cause serious problems. It can, for example, cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to know that the risk of a heart attack or stroke from using NuvaRing is very small, but it can increase:

- with increasing age (above about 35 years)

- if you smoke. If you use a combined hormonal contraceptive like NuvaRing, it is advised that you stop smoking. If you cannot stop smoking and are over 35 years old, your doctor may advise you to use a different type of contraceptive.

- if you are overweight

- if you have high blood pressure

- if a member of your immediate family has had a heart attack or stroke at a young age (before the age of 50)^e years). In that case, you may also have an increased risk of having a heart attack or stroke.

- if you, or a member of your immediate family, have high levels of fat in the blood (cholesterol or triglycerides)

- if you suffer from migraines, especially migraines with aura

- if you have a heart condition (heart valve disorder, or a heart rhythm disorder called atrial fibrillation)

- if you have diabetes.

If more than one of these conditions applies to you, or if one of these conditions is particularly severe, the risk of developing a blood clot may be further increased.

If any of the above conditions change while you are using NuvaRing, for example, if you start smoking or if a close family member develops a blood clot (thrombosis) without a known cause, or if you gain a lot of weight, inform your doctor.

Cancer

The following information is obtained from studies with other combined hormonal contraceptives (the pill) but may also apply to NuvaRing. There are no specific data available on the vaginal administration form of hormonal contraceptives (such as with NuvaRing).

Breast cancer has been diagnosed slightly more often in women using the pill than in non-users, but it is not known if this difference is caused by the pill. A possible reason could be that pill users are examined more frequently by the doctor, so breast cancer is detected earlier. After stopping the pill, the increased risk of breast cancer gradually decreases until there is no difference.

It is important to regularly perform self-breast examinations. If you feel a lump, contact your doctor. Also, if a direct family member has or has had breast cancer, you should inform your doctor (see also section 2 'When should you be extra careful with this medicine?').

In rare cases, benign liver tumors have been found in pill users and, in even rarer cases, malignant liver tumors. If you suddenly experience severe abdominal pain, contact your doctor immediately.

It has been reported that endometrial cancer and ovarian cancer occur less frequently in pill users than in non-users. Although this may also be the case with NuvaRing, this is not yet established.

Psychiatric disorders

Some women using hormonal contraceptives, including NuvaRing, have reported depression or mood swings. Depression can be severe and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor as soon as possible for further medical advice.

Children and adolescents up to 18 years

The safety and efficacy of NuvaRing have not been studied in adolescents under 18 years.

Are you using any other medications?

Always inform your doctor about any medications and herbal remedies you are already using. Also, inform any other doctor or dentist who prescribes you another medication (or the pharmacist) that you are taking this medicine. They can tell you if it is necessary to take extra contraceptive measures (such as male condoms) and, if so, how long you need to do this and whether the use of other medications you need should be adjusted.

Some medications

- can affect the blood levels of NuvaRing
- can reduce protection against pregnancy
- can cause unexpected bleeding.

These include medications used in the treatment of:

epilepsy (for example, primidone, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate)
tuberculosis (for example rifampicin)
HIV infection (for example ritonavir, nelfinavir, nevirapine, efavirenz)
hepatitis C virus infection (for example boceprevir, telaprevir)
other infections (for example griseofulvin)
high blood pressure in the blood vessels of the lungs (bosentan)
depressive moods (the herbal remedy St. John's wort).

If you are using medicines or herbal remedies that can make NuvaRing less reliable, you should also use a barrier contraceptive (for example a male condom). Since the effect of another medicine on NuvaRing can last up to 28 days after stopping that medicine, you should continue to use this additional barrier contraceptive during that time. Note: Do not use NuvaRing with a female condom or diaphragm.

NuvaRing can affect the action of other medicines, for example

- medicines containing cyclosporine
- the anti-epileptic lamotrigine (this can lead to an increased number of seizures).

Do not use NuvaRing if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir because this

can cause an increase in the results of a liver function blood test (increase in ALT, a liver enzyme).

Your doctor will prescribe another contraceptive before you start this treatment.

NuvaRing can be restarted approximately two weeks after the end of this treatment. See section 2 'When should you not use this medicine?'

Ask your doctor or pharmacist for advice before using any medicine.

You can use tampons together with NuvaRing. Insert NuvaRing first before inserting a tampon. Be careful not to accidentally remove NuvaRing when removing the tampon. If this happens, rinse NuvaRing with cold to lukewarm water (do not use hot water) and reinsert the ring immediately.

The breaking of the ring has occurred with simultaneous use of a vaginal product, such as a lubricant or a product for the treatment of an infection (see section 3 'What to do if... NuvaRing breaks'). The effectiveness of NuvaRing is not affected by the use of spermicides or products for the treatment of vaginal yeast infections.

Laboratory tests

If you need to undergo a blood or urine test, inform the attending physician that you are using NuvaRing, as this may affect the results of some tests.

Pregnancy and breastfeeding

If you are pregnant, or think you might be pregnant, you should not use NuvaRing. If you become pregnant while using NuvaRing, you must remove the ring and contact your doctor.

If you want to stop using NuvaRing because you want to become pregnant, please read section 3 'If you want to stop using NuvaRing'.

The use of NuvaRing is generally not recommended while you are breastfeeding. Contact your doctor if you want to use NuvaRing while you are still breastfeeding.

Driving and using machines

It is unlikely that the use of NuvaRing will affect your ability to drive and use machines.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

You can insert and remove NuvaRing yourself. Your doctor will tell you when you can start with NuvaRing. The vaginal ring must be inserted on the correct day of the menstrual cycle (see section 3 'When to start with the first ring?') and then remains in the vagina continuously for 3 weeks. Regularly check the presence of NuvaRing in the vagina (for example, before and after intercourse) to ensure you are protected against

pregnancy. After wearing the ring for 3 weeks, you remove the ring and do not use a ring for 1 week. During this ring-free week, your monthly bleeding usually begins.

If you are using NuvaRing and temporarily need to use an additional barrier contraceptive, do not use a female condom or diaphragm. The presence of NuvaRing in the vagina may prevent the female condom or diaphragm from being inserted properly. However, you can use a male condom as an additional barrier contraceptive.

How can you insert and remove NuvaRing?

1. Check before inserting the ring that the expiration date has not been exceeded (see section 5 'How to store this medicine?').
2. Wash your hands before inserting or removing the ring.
3. Choose a position that you find comfortable for inserting the ring, such as standing with one leg up, squatting, or lying down.
4. Remove NuvaRing from the sachet.
5. Hold the ring between your thumb and index finger, press the ring together and insert it into the vagina (see figures 1-4). Alternatively, you can choose to use the NuvaRing Applicator (not included with NuvaRing) to help you insert the ring. The NuvaRing Applicator is not available in all countries. If the ring is in the right place, you will not feel it. If the ring does not feel comfortable, move the ring (for example, gently push it a little further) until it feels comfortable. The exact position of the ring in the vagina is not important.
6. After 3 weeks, remove NuvaRing from the vagina. You can do this by hooking your index finger through the ring or by grasping the ring between your index and middle finger and pulling it out (see figure 5). If you can find the ring in the vagina but cannot remove it, you should contact your doctor.
7. The used ring can be disposed of with normal household waste, preferably in the resealable bag. Do not flush NuvaRing down the toilet.

Figure 1
Remove NuvaRing from the sachet

Image 2
Compress the ring

Image 3
Choose a comfortable position to insert the ring

Image 4A Image 4B Image 4C

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

Image 5
NuvaRing can be removed by hooking the index finger through the ring or by grasping the ring between the index and middle finger and pulling it out

Three weeks in, one week out

1. From the day of insertion of NuvaRing, you wear the ring for 3 weeks without interruption.
2. After those 3 weeks, you remove the ring again, on the same day of the week and at approximately the same time as you inserted it. For example, if you inserted NuvaRing on Wednesday evening around 10 o'clock, it means you should remove the ring 3 weeks later on Wednesday evening around 10 o'clock.
3. After you have removed the ring, you do not use a ring for 1 week. During this week, a bleeding should begin. This usually starts on the 2nd or 3rd day after removing NuvaRing.
4. Start with a new ring after exactly 1 week (again on the same day and at approximately the same time), even if the bleeding has not yet stopped. If the ring is inserted more than 3 hours late, its reliability may be reduced. In that case, follow the instructions in section 3 'What to do if... You forgot to insert a new ring after the ring-free period'.

If you use NuvaRing as described above, your monthly bleeding will occur approximately on the same days each time.

When to start with the first ring?

You have not used a hormonal contraceptive in the past month

Insert the first NuvaRing on the first day of your period. NuvaRing works immediately. You do not need to use an additional contraceptive.

Starting between day 2 and day 5 of your period is also allowed, but make sure to use an additional contraceptive (e.g., a male condom) during the first 7 days of this first cycle.

You have used a combined pill in the past month

You must start with NuvaRing at the latest on the day after the tablet-free period of the pill ends. If your pill pack also contains inactive tablets, you must start with NuvaRing at the latest on the day after the last inactive tablet. If you are unsure which tablet that is, ask your doctor or pharmacist. In no case should you exceed the normal length of the hormone-free period.

When you have used the pill fully according to the instructions and you are certain that you are not pregnant, you can stop taking the pill on any day of your current cycle and immediately switch to using NuvaRing.

You have used a contraceptive patch in the past month

You must start with NuvaRing at the latest seven days after removing the last patch. In no case should you exceed the normal length of the patch-free period. When you have used the patch fully according to the instructions and you are certain that you are not pregnant, you can stop using the patch on any day of your current cycle and immediately switch to using NuvaRing.

You have used a mini-pill (progestogen-only pill) in the past month

You can switch to NuvaRing from one day to the next, at the same time you would have taken the pill, but you must use an additional contraceptive (e.g., a male condom) for the first 7 days.

You have used an injection, implant, or hormone-releasing IUD in the past month

Start with NuvaRing when you would otherwise receive the next injection or on the day the implant or hormone-releasing IUD is removed. However, you must use an additional contraceptive method (e.g., a male condom) for the first 7 days.

After childbirth

If you have just given birth, your doctor will likely advise you to wait until your first spontaneous menstruation. Sometimes it is possible to start with NuvaRing earlier. Follow your doctor's advice. This also applies if you are breastfeeding and want to use NuvaRing.

After a miscarriage or abortion

Follow your doctor's advice.

What to do if...

NuvaRing accidentally comes out of the vagina

NuvaRing can accidentally come out of the vagina, for example, if it is not inserted high enough, when you remove a tampon, during intercourse, or with difficult bowel movements or constipation. It can also happen if you have a prolapse of the cervix, for example. Therefore, you are advised to regularly check if the ring is still in the vagina (e.g., before and after intercourse).

NuvaRing has been temporarily out of the vagina

NuvaRing can still protect you against pregnancy, depending on how long the ring has been out of your vagina.

If the ring has been out of the vagina for less than 3 hours, the effectiveness of the ring is not reduced. Rinse the ring with cold to lukewarm water (do not use hot water) and reinsert the ring as soon as possible, but only if the ring has been out of the vagina for less than 3 hours.

If the ring has been out of the vagina for more than 3 hours during the first or second week of the ring period, the effectiveness of the ring may be reduced. Rinse the ring with cold to lukewarm water (do not use hot water) and reinsert it into the vagina as soon as you remember and do not remove it until you have had the ring in for at least 7 consecutive days. Use additional contraceptives during these 7 days, such as a

male condom. If the ring has been out for more than 3 hours during the first week of use and you have had intercourse in the seven days prior, you should consider the possibility of pregnancy. In that case, contact your doctor.

If the ring has been out of the vagina for more than 3 hours during the third week of the ring period, the effectiveness of the ring may be reduced. You must discard this ring and choose between the following two options:

1. Insert a new ring immediately.

By inserting a new ring, you start a new ring period of 3 weeks. You will not have a withdrawal bleed. A breakthrough bleeding or spotting (drops or blood spots) may occur.

2. Do not reinsert the ring.

Wait for your withdrawal bleed and insert a new ring within 7 days after removing or losing the previous ring.

You can only choose this option if you have used the ring continuously during the previous 7 days.

If the ring has been out of the vagina for an unknown period, you have not been protected against pregnancy. Take a pregnancy test and consult your doctor before inserting a new ring.

NuvaRing breaks

Very rarely, NuvaRing may break. Vaginal injury due to the ring breaking has been reported. If you notice this, discard the broken ring and replace it with a new ring as soon as possible. Use additional contraceptives, such as a male condom, for the next 7 days. If you had intercourse before noticing the ring was broken, contact your doctor.

You have inserted more than 1 ring

There are no reports of serious harmful effects from an overdose of the hormones in NuvaRing. If you accidentally inserted more than 1 ring, you may experience nausea, vomiting, or vaginal bleeding. Remove the excess rings and contact your doctor if the above symptoms persist.

You forgot to insert a new ring after the ring-free period

If your ring-free period was longer than 7 days, you should insert a new ring into the vagina as soon as you remember. You must use additional contraceptives (such as a male condom) for 7 days. If you had intercourse during the ring-free period, you should consider the possibility of a pregnancy. In that case, contact your doctor immediately. The longer the ring-free period, the greater the chance of pregnancy.

You forgot to remove the ring

If the ring has been in the vagina for more than 3, but up to 4 weeks, the effectiveness of the ring is not reduced. Take a ring-free period of up to 7 days and then insert a new ring.

If the ring has been in the vagina for more than 4 weeks, the effectiveness of the ring may be reduced and you may become pregnant. In that case, contact your doctor before starting a new ring.

The expected menstruation does not occur

You have used NuvaRing correctly

If you have used NuvaRing correctly and have not used other medications, it is highly unlikely that you are pregnant. You can safely continue with the next ring. However, if the expected bleeding does not occur twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next NuvaRing until your doctor has confirmed that you are not pregnant.

You have not used NuvaRing correctly

If you have deviated from the recommended use and you do not have the expected bleeding in the next ring-free period, you may be pregnant. Contact your doctor before starting the next NuvaRing.

Unexpected bleeding occurs

Sometimes unexpected bleeding may occur after you have previously menstruated normally and have used NuvaRing correctly. You may not be able to do without

sanitary protection. In any case, leave your ring in the vagina. If the bleeding lasts longer, worsens, or starts again, you should contact your doctor.

You want to change the start day of your menstruation

If you use NuvaRing as directed, your menstruation (withdrawal bleeding) will start on approximately the same day in the ring-free week each time. If you want to change this day, you can do so by shortening the ring-free period (but never by extending it!).

For example, if your period normally starts on a Friday, you can shift it to Tuesday (3 days earlier) from the next month. You simply need to start a new ring 3 days earlier than usual.

If you make the ring-free period very short (for example, 3 days or less), you may not have a bleeding during this ring-free period. You may then experience spotting or breakthrough bleeding while using the next ring.

Ask your doctor for advice if you have any questions about this.

You want to delay your period

Although this is not the prescribed use, you can delay your period (withdrawal bleeding) by immediately continuing with a new NuvaRing after removing the ring without the ring-free week. You can use this new ring again as usual for up to 3 weeks. You may experience spotting or breakthrough bleeding while using this new ring. If you want your period to start, you can simply remove the ring. Then insert the new ring after the ring-free week.

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

You want to stop using NuvaRing You can stop using NuvaRing whenever you want.

If you do not want to become pregnant, ask your doctor for advice on other reliable methods of birth control.

If you stop because you want to become pregnant, wait until you have had a natural period before trying to conceive. This will make it easier to calculate when the delivery will take place.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. If you experience a side effect, especially if it is severe or persistent, or if there is a change in your health that you think may be caused by NuvaRing, contact your doctor.

All women using combined hormonal contraceptives have a higher risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]). For more information on the different risks of using combined hormonal contraceptives, see section 2 'When should you not use this medicine or be extra careful with it?'

If you are allergic to any of the ingredients in NuvaRing, you may experience the following symptoms (frequency not known): life-threatening allergic reaction (anaphylaxis) and/or angioedema (swelling of the face, lips, tongue, and/or throat and/or difficulty swallowing) or hives possibly with breathing problems. If you experience these, remove NuvaRing and contact your doctor immediately (see also section 2 'When should you be extra careful with this medicine?').

The following side effects have been reported by users of NuvaRing:

Common: occur in less than 1 in 10 women

abdominal pain, nausea
yeast infection of the vagina (such as thrush), vaginal discomfort due to the ring, itching of the genital area, vaginal discharge
headache or migraine, depression, decreased libido
breast pain, pelvic pain, painful menstruation
acne
weight gain
loss of the ring

Sometimes: occur in less than 1 in 100 women

visual disturbance, dizziness
bloated abdomen, vomiting, diarrhea, constipation
feelings of fatigue, being unwell or irritability, mood changes, mood swings
fluid retention (edema)
urinary tract infections or cystitis
difficulty or painful urination, strong and frequent urge to urinate
problems during intercourse, such as pain, bleeding, or the partner feeling the ring
increased blood pressure
increased appetite
back pain, muscle contractions, pain in legs or arms
less sensitive skin
painful or larger breasts, formation of benign lumps in the breast that can become swollen and painful (fibroadenoma)
inflammation of the cervix, cervical polyps, protrusion of the cervical mucosa (ectropion)
changes in menstruation (e.g., heavy, prolonged, irregular, or absent menstruation), pelvic pain, premenstrual syndrome, uterine contractions
vaginal infection (fungal and/or bacterial), burning sensation, odor, pain, discomfort, or dryness of the vagina
hair loss, eczema, itching, rash, or hot flashes
rash on the skin with pink bumps and severe itching (hives)

Rare: occur in less than 1 in 1000 women

harmful blood clots in a vein or artery, for example:

- o in a leg or foot (e.g., deep vein thrombosis)
- o in a lung (e.g., pulmonary embolism)
- o heart attack
- o stroke

- o 'mini-stroke' or temporary symptoms similar to a stroke, known as TIA (transient ischemic attack)
- o blood clots in the liver, stomach/intestines, kidneys, or eyes.

The risk of developing a blood clot is higher if other conditions apply to you that increase this risk (see section 2 for more information on conditions that increase the risk of blood clots and the symptoms of a blood clot)

breast discharge

Not known: frequency cannot be determined from the available data

chloasma (yellow-brown pigment spots, so-called 'pregnancy spots', especially on the face)

conditions of the partner's penis (such as itching, irritation, and rash)

unable to remove the ring without medical assistance (for example, due to adherence to vaginal tissue)

vaginal injury due to the ring breaking.

Breast cancer and liver tumors have been reported in women using combined hormonal contraceptives. For more information, see section 2 'When should you be extra careful with this medicine?'

Very rarely, NuvaRing breaks. For more information, see the section 'What to do if... NuvaRing breaks'.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

If you discover that a child has been exposed to the hormones from the ring, ask your doctor for advice.

Store below 30 °C. Store in the original package to protect from light and moisture.

Do not use a NuvaRing if it was supplied to you more than 4 months ago. The delivery date is indicated on the box and sachet.

Do not use NuvaRing after the expiry date. This can be found on the box and sachet after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not use NuvaRing if you notice that the ring is discolored or if you observe other visible signs of deterioration in quality.

Dispose of the used ring in the trash, preferably in the resealable sachet. Do not flush down the toilet. As with other medicines, do not flush unused rings or rings past their expiry date down the sink or toilet and do not throw them in the trash. Ask your

pharmacist what to do with unused rings you no longer wish to use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substances in this medicine are: etonogestrel (11.7 mg) and ethinylestradiol (2.7 mg)

The other substances in this medicine are: ethylene vinyl acetate copolymers (28% and 9% vinyl acetate) (a type of plastic not absorbed by the body) and magnesium stearate.

Every day for three weeks, 0.120 mg of etonogestrel and 0.015 mg of ethinylestradiol are released by the ring.

What does NuvaRing look like and what is in a package?

NuvaRing is a flexible, transparent, colorless to almost colorless ring with a diameter of 54 mm.

Each ring is packaged in a resealable sachet made of aluminum foil. The sachets are packed in a cardboard box along with this leaflet. A box contains 1 or 3 rings. Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

N.V. Organon

Kloosterstraat 6

5349 AB Oss

Netherlands

Tel.: 00800 66550123 (+32 2 2418100)

E-mail: dpoc.benelux@organon.com

Registered under RVG 25073.

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following name:

NuvaRing

Belgium, Denmark, Germany, Estonia, Finland, France, Greece, Hungary, Ireland, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Czech Republic, United Kingdom (Northern Ireland), Sweden.

This leaflet was last approved in {month yyyy}.