

condoms or spermicide, **MUST** be used until a new NuvaRing[®] has been used **continuously for seven days**.

In the event of a missed menstrual period

1. If the woman has not adhered to the prescribed regimen (NuvaRing[®] has been out of the vagina for more than three hours or the preceding ring-free interval was extended beyond one week) the possibility of pregnancy should be considered at the time of the first missed period and NuvaRing[®] use should be discontinued if pregnancy is confirmed.
2. If the woman has adhered to the prescribed regimen and misses two consecutive periods, pregnancy should be ruled out.
3. If the woman has retained one NuvaRing[®] for longer than four weeks, pregnancy should be ruled out.

HOW SUPPLIED

Each NuvaRing[®] (etonogestrel/ethinyl estradiol vaginal ring) is individually packaged in a reclosable aluminum laminate sachet consisting of three layers, from outside to inside: polyester, aluminum foil, and low-density polyethylene. The ring should be replaced in this reclosable sachet after use for convenient disposal.

Box of 3 sachets NDC 0052-0273-03
Box of 1 sachet NDC 0052-0273-01

Storage

Prior to dispensing to the user, store refrigerated 2–8°C (36–46°F). After dispensing to the user, NuvaRing[®] can be stored for up to four months at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Avoid storing NuvaRing[®] in direct sunlight or at temperatures above 30°C (86°F). For the Dispenser: When NuvaRing[®] is dispensed to the user, place an expiration date on the label. The date should not exceed either four months from the date of dispensing or the expiration date, whichever comes first.

Rx only

REFERENCES FURNISHED UPON REQUEST

PATIENT INFORMATION

NuvaRing[®] (etonogestrel/ethinyl estradiol vaginal ring)

Rx only

Read this leaflet carefully before you use NuvaRing[®] so that you understand the benefits and risks of using this form of birth control. The leaflet gives you information about the possible serious side effects of NuvaRing[®]. This leaflet will also tell you how to use NuvaRing[®] properly so that it will give you the best possible protection against pregnancy. Read the information you get whenever you get a new prescription or refill, because there may be new information. This information does not take the place of talking with your healthcare provider.

What is NuvaRing®?

NuvaRing® (NEW-vah-ring) is a flexible combined contraceptive vaginal ring. It is used to prevent pregnancy. **It does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STD's) such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.**

NuvaRing® contains a combination of a progestin and estrogen, two kinds of female hormones. You insert the ring in your vagina and leave it there for three weeks. After the ring is inserted, it releases a continuous low dose of hormones into your body. You then remove it for a one-week ring-free period.

Contraceptives that contain both an estrogen and a progestin are called combination hormonal contraceptives. Most studies on combination contraceptives have used oral (taken by mouth) contraceptives. NuvaRing® may have the same risks that have been found for combination oral contraceptives. This leaflet will tell you about risks of taking combination oral contraceptives that may also apply to NuvaRing® users. In addition, it will tell you how to use NuvaRing® properly so that it will give you the best possible protection against pregnancy.

Who should not use NuvaRing®?

Cigarette smoking increases the risk of serious cardiovascular side effects when you use combination oral contraceptives. This risk increases even more if you are over age 35 and if you smoke 15 or more cigarettes a day. Women who use combination hormonal contraceptives, including NuvaRing®, are strongly advised not to smoke.

Do not use **NuvaRing®** if you have any of the following conditions:

- a history of heart attack or stroke
- a history of blood clots in your legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- a history of blood clots in the deep veins of your legs
- chest pain (angina pectoris)
- severe high blood pressure
- diabetes with complications of the kidneys, eyes, nerves, or blood vessels
- headaches with neurological symptoms
- known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina (now or in the past)
- unexplained vaginal bleeding (until a diagnosis is reached by your healthcare provider)
- yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of hormonal birth control of any kind (the pill, patch, vaginal ring, injection, or implant)
- liver tumor (benign or cancerous)
- heart valve or heart rhythm disorders that may be associated with formation of bloods clots
- need for a long period of bed rest following major surgery
- known or suspected pregnancy
- active liver disease with abnormal liver function tests
- an allergy or hypersensitivity to any of the components of NuvaRing®

Tell your healthcare provider if you have ever had any of the conditions just listed. Your healthcare provider can suggest another method of birth control.

Talk with your healthcare provider about using NuvaRing® if you:

- smoke
- recently had a baby
- recently had a miscarriage or abortion
- are breastfeeding

- are taking other medications

In addition, talk to your healthcare provider about using NuvaRing[®] if you have any of the following conditions. Women with any of these conditions should be checked often by their doctor or healthcare provider if they choose to use NuvaRing[®].

- a family history of breast cancer
- breast nodules, fibrocystic disease, an abnormal breast x-ray, or abnormal mammogram
- diabetes
- elevated cholesterol or triglycerides
- high blood pressure
- migraine or other headaches or epilepsy
- depression
- gallbladder, liver, heart, or kidney disease
- scanty or irregular menstrual periods
- plan to have major surgery (You may need to stop using NuvaRing[®] for a while to reduce your chance of getting blood clots.)
- any condition that makes the vagina get irritated easily
- prolapsed (dropped) uterus, dropped bladder (cystocele), or rectal prolapse (rectocele)
- severe constipation
- history of toxic shock syndrome

How should I use NuvaRing[®]?

For the best protection from pregnancy, use NuvaRing[®] exactly as directed. Insert one NuvaRing[®] in the vagina and **keep it in place for three weeks in a row**. Remove it for a one-week break and then insert a new ring. During the one-week break, you will usually have your menstrual period. Your healthcare provider should examine you at least once a year to see if there are any signs of side effects of NuvaRing[®] use.

When should I start NuvaRing[®]?

Follow the instructions in one of the sections below to find out when to start using NuvaRing[®]:

If you **did not use a hormonal contraceptive in the preceding cycle**

Insert NuvaRing[®] on the first day of your cycle, (i.e., the first day of menstrual bleeding). NuvaRing[®] will work immediately, it is not necessary to use an additional contraceptive method. You may also start on days 2-5 of your cycle, but in this case make sure you also use an extra method of birth control (barrier method), such as male condoms or spermicide for the first seven days of NuvaRing[®] use in the first cycle.

If you are changing from a combined hormonal contraceptive pill or patch (containing both progestin and estrogen)

Switch from your previous combined hormonal contraceptive on any day, but at the latest on the day following the usual hormone-free interval by inserting NuvaRing[®]. If you have been using your hormonal contraceptive method consistently and correctly, no extra birth control method should be needed.

If you are changing from a progestagen-only method (minipill, implant or injection) or from a progestagen-releasing intrauterine system (IUS)

You may switch on any day from a minipill. You should switch from an implant or the IUS on the day of its removal and from an injectable on the day when the next injection would be due. In all of

these cases, you should use an extra method of birth control, such as a male condom or spermicide, for the first seven days of ring use.

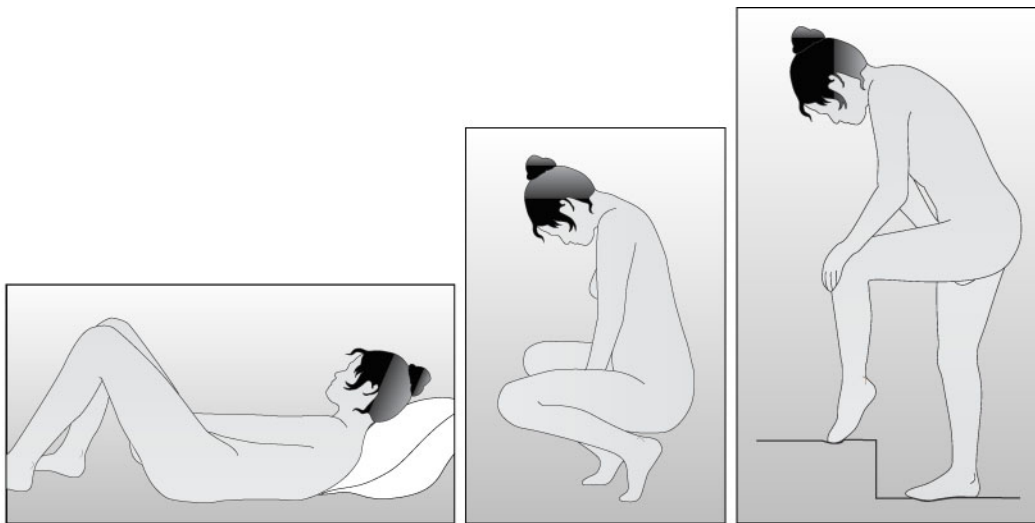
Following first trimester abortion or miscarriage

If you start using NuvaRing[®] within five days after a complete first trimester abortion or miscarriage, you do not need to use an extra method of contraception.

If NuvaRing[®] is not started within five days after a first trimester abortion or miscarriage, begin NuvaRing[®] at the time of your next menstrual period. Counting the first day of your menstrual period as “Day 1”, insert NuvaRing[®] on or before Day 5 of the cycle, even if you have not finished bleeding. During this first cycle, use an extra method of birth control, such as male condoms or spermicide, for the first seven days of ring use.

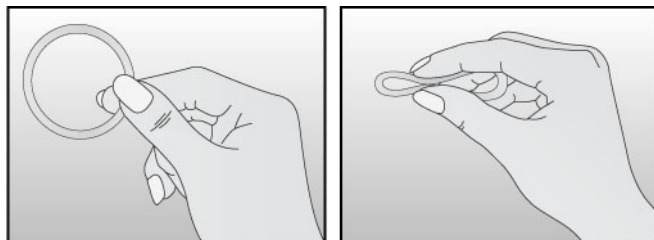
How do I insert NuvaRing[®]?

1. Each NuvaRing[®] comes in a reclosable foil pouch. After washing and drying your hands, remove NuvaRing[®] from its foil pouch. Keep the foil pouch for proper disposal of the ring after use. Choose the position that is most comfortable for you. For example, lying down, squatting, or standing with one leg up (Figures 1a, 1b, and 1c, respectively).



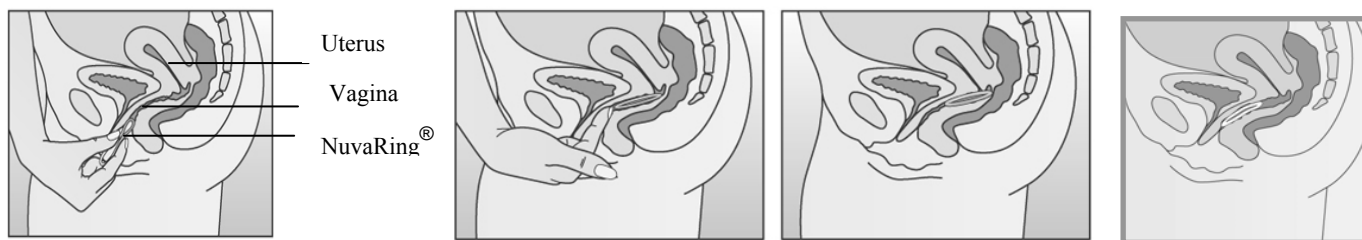
Figures 1a, 1b, and 1c. Positions for NuvaRing[®] insertion.

2. Hold NuvaRing[®] between your thumb and index finger (Figure 2a) and press the opposite sides of the ring together (Figure 2b).



Figures 2a and 2b. Holding NuvaRing[®] and pressing the sides together.

3. Gently push the folded ring into your vagina (Figures 3a and 3b). The exact position of NuvaRing[®] in the vagina is not important for it to work (Figures 3c and 3d).



Figures 3a, 3b, 3c, and 3d. Inserting and positioning of NuvaRing[®].

Although some women may be aware of NuvaRing[®] in the vagina, most women do not feel it once it is in place. If you feel discomfort, NuvaRing[®] is probably not inserted back far enough in the vagina. Use your finger to gently push the NuvaRing[®] farther into your vagina. **There is no danger of NuvaRing[®] being pushed too far up in the vagina or getting lost.** NuvaRing[®] can be inserted only as far as the end of the vagina, where the cervix (the narrow, lower end of the uterus) will block NuvaRing[®] from going any farther.

4. Once inserted, keep NuvaRing[®] in place for three weeks in a row.

How do I remove NuvaRing[®]?



Figure 4. Removing NuvaRing[®].

1. Remove the ring three weeks after insertion on the same day of the week as it was inserted, at about the same time of day.

You can remove NuvaRing[®] by hooking the index finger under the forward rim or by holding the rim between the index and middle finger and pulling it out (Figure 4).

2. Place the used ring in the foil pouch and properly dispose of it in a waste receptacle out of the reach of children and pets. Do not throw it in the toilet.

Your menstrual period will usually start two to three days after the ring is removed and may not have finished before the next ring is inserted. **To continue to have pregnancy protection, you must insert the new ring one week after the last one was removed, even if your menstrual period has not stopped.**

If you locate the ring in your vagina but are unable to remove it, please contact your healthcare provider.

When do I insert a new ring?

After no more than a one-week ring-free break, insert a new ring on the same day of the week as it was removed in the last cycle. If the ring-free interval has been extended beyond one week, the possibility of pregnancy should be considered, and an extra method of birth control, such as male condoms or spermicide, **MUST** be used until NuvaRing[®] has been used **continuously for seven days**.

If NuvaRing[®] slips out:

NuvaRing[®] can accidentally slip out of the vagina while removing a tampon, during intercourse, or straining during a bowel movement. If NuvaRing[®] slips out of the vagina **and it has been out for less than three hours**, you should still be protected from pregnancy. NuvaRing[®] can be rinsed with cool to lukewarm (not hot) water and reinserted as soon as possible, and at the latest within three hours of removal or expulsion (slipping out).

If NuvaRing[®] is out of the vagina for more than three continuous hours:

During Weeks 1 and 2: If the ring **has been out of the vagina for more than three continuous hours** during the 1st or 2nd week of use, contraceptive effectiveness may be reduced. Reinsert ring as soon as you remember and use an extra method of birth control, such as male condoms or spermicide, until the ring has been used continuously for seven days.

During Week 3: If NuvaRing[®] slips **out of the vagina for more than three continuous hours** during the 3rd week of the three-week use period, throw the ring away and choose one of the following two options.

1. Insert a new ring immediately. Inserting a new ring will start the next three-week use period. You may not experience a period from your previous cycle. However, breakthrough spotting or bleeding may occur.
2. Have your period and insert a new ring no later than seven days (7x24 hours) from the time the previous ring was removed or expelled. This option should only be chosen if the ring was used continuously for the preceding seven days.

In addition, a barrier method such as condoms or spermicides must be used until the ring has been used continuously for seven days.

Women with conditions affecting the vagina, such as a prolapsed (dropped) uterus, may be more likely to have NuvaRing[®] slip out of the vagina. If NuvaRing[®] slips out repeatedly, you should consult with your healthcare provider.

If NuvaRing[®] is in your vagina too long:

If NuvaRing[®] has been left in your vagina for an extra week or less (four weeks total or less), you will remain protected. Remove NuvaRing[®] and insert a new ring after a one-week ring-free break.

If NuvaRing[®] has been left in place for more than four weeks, you may not be adequately protected from pregnancy and you must check to be sure you are not pregnant. You **MUST** use an extra method of birth control, such as male condoms or spermicide, until the new NuvaRing[®] has been in place for **seven days in a row**.

If you miss a menstrual period:

You must check to be sure that you are not pregnant if:

1. you miss a period and NuvaRing[®] was out of the vagina for more than three hours during the three weeks of ring use
2. you miss a period and waited longer than one week to insert a new ring
3. you have followed the instructions and you miss two periods in a row
4. you have left NuvaRing[®] in place for longer than four weeks

Can I use tampons when using NuvaRing[®]?

Use of tampons will not reduce the contraceptive efficacy of NuvaRing[®]. Insert NuvaRing[®] before inserting a tampon. You should pay particular attention when removing a tampon to be sure that the ring is not accidentally pulled out. If this should occur, simply rinse the ring in cool to lukewarm (not hot) water and immediately reinsert it.

Can I use vaginal medications?

Use of spermicides or vaginal yeast products will not reduce the contraceptive efficacy of NuvaRing[®].

What should I do if my NuvaRing[®] disconnects?

There have been reported cases of NuvaRing[®] disconnecting at the weld joint causing the ring to change shape and straighten out. This is not expected to affect the contraceptive effectiveness of NuvaRing[®]. If NuvaRing[®] disconnects, expulsion (slipping out) is more likely to occur (see “If NuvaRing[®] slips out”). If you discover the ring has disconnected, you should discard the ring and replace it with a new ring.

Overdose

NuvaRing[®] is unlikely to cause an overdose because the ring holding the medicine releases a steady amount of contraceptive hormones. Do not use more than one ring at a time. Overdose of combination hormonal contraceptives may cause nausea, vomiting, or vaginal bleeding.

What should I avoid while using NuvaRing[®]?

Cigarette smoking increases the risk of serious cardiovascular side effects when you use combination oral contraceptives, including NuvaRing[®]. This risk increases even more if you are over age 35 and if you smoke 15 or more cigarettes a day. Women who use combination hormonal contraceptives, like NuvaRing[®], are strongly advised not to smoke.

Do not breast-feed while using NuvaRing[®]. Some of the medicine may pass through the milk to the baby and could cause yellowing of the skin (jaundice) and breast enlargement in your baby. NuvaRing[®] could also decrease the amount and quality of your breast milk.

The hormones in NuvaRing[®] can interact with many other medicines and herbal supplements. Tell your healthcare provider about any medicines you are taking, including prescription medicines, over-the-counter medicines, herbal remedies, and vitamins.

The blood levels of the hormones released by NuvaRing[®] were increased when women used a vaginal medication (miconazole nitrate) for a yeast infection while NuvaRing[®] was in place. The pregnancy protection of NuvaRing[®] is not likely to be changed by use of these products. The blood levels of these hormones were not changed when women used vaginal, water-based spermicides (nonoxynol or N-9 products) along with NuvaRing[®].

Certain drugs and herbal supplements may interact with combined hormonal contraceptives to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin, drugs used for epilepsy such as barbiturates (for example, phenobarbital), carbamazepine, and phenytoin, primidone, topiramate, phenylbutazone, modafinil, and some drugs used for HIV such as ritonavir. Pregnancies and breakthrough bleeding have been reported by users of combined hormonal contraceptives who also used the herbal supplement St. John's Wort. You may need to use a non-hormonal method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective. Be sure to tell your healthcare provider if you are taking or start taking any other medications, including non-prescription products or herbal products while using NuvaRing®.

While using NuvaRing®, you should not rely upon a diaphragm when you need a back-up method of birth control because NuvaRing® may interfere with the correct placement and position of a diaphragm.

If you are scheduled for any laboratory tests, tell your doctor or healthcare provider you are using NuvaRing®. Contraceptive hormones may change certain blood tests results.

What are the possible risks and side effects of NuvaRing®?

• Blood clots

The hormones in NuvaRing® may cause changes in your blood clotting system which may allow your blood to clot more easily. If blood clots form in your legs, they can travel to the lungs and cause a sudden blockage of a vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or other vision problems. The risk of getting blood clots may be greater with the type of progestin in NuvaRing® than with some other progestins in certain low-dose birth control pills. It is unknown if the risk of blood clots is different with NuvaRing® use than with the use of certain birth control pills.

If you take hormonal contraceptives and need elective surgery, need to stay in bed for a prolonged illness or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your doctor or health care provider about stopping hormonal contraceptives three to four weeks before surgery and not taking hormonal contraceptives for two weeks after surgery or during bed rest. You should also not take hormonal contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery if you are not breast feeding. If you are breast feeding, you should wait until you have weaned your child before using the pill (see PRECAUTIONS, NURSING MOTHERS).

• Strokes and heart attacks

Hormonal contraceptives may increase your risk of strokes (blockage of blood flow to the brain) or heart attacks (blockage of blood flow to the heart). Any of these conditions can cause death or serious disability. Smoking greatly increases the risk of having strokes and heart attacks. Furthermore, smoking and the use of combination hormonal contraceptives, like NuvaRing®, greatly increases the chances of developing and dying of heart disease. If you use combination hormonal contraceptives, including NuvaRing®, you should not smoke.

• High blood pressure and heart disease

Combination hormonal contraceptives, including NuvaRing®, can worsen conditions like high blood pressure, diabetes, and problems with cholesterol and triglycerides.

• Cancer of the reproductive organs and breast

Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This small increase in the number of breast cancer diagnoses gradually disappears during the 10 years after stopping use of the pill. It is not known whether the

difference is caused by the pill. It may be that women taking the pill are examined more often, so that breast cancer is more likely to be detected. You should have regular breast examinations by a healthcare provider and examine your own breasts monthly. Tell your healthcare provider if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram.

Women who currently have or have had breast cancer should not use hormonal contraceptives, including NuvaRing[®], because breast cancer is usually a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

- **Gallbladder disease**

Combination hormonal contraceptive users may have a higher chance of having gallbladder disease.

- **Liver tumors**

In rare cases, combination hormonal contraceptives, like NuvaRing[®], can cause non-cancerous (benign) but dangerous liver tumors. These benign liver tumors can break and cause fatal internal bleeding. In addition, it is possible that women who use combination hormonal contraceptives, like NuvaRing[®], have a higher chance of getting liver cancer. However, liver cancers are extremely rare.

- **Lipid metabolism and inflammation of the pancreas**

In women with inherited defects of lipid metabolism, there have been reports of significant elevations of plasma triglycerides during estrogen therapy. This has led to pancreatitis in some cases.

The common side effects reported by NuvaRing[®] users are:

- vaginal infections and irritation
- vaginal secretion
- headache
- weight gain
- nausea

In addition to the risks and side effects listed above, users of combination hormonal contraceptives have reported the following side effects:

- vomiting
- change in appetite
- abdominal cramps and bloating
- breast tenderness or enlargement
- irregular vaginal bleeding or spotting
- changes in menstrual cycle
- temporary infertility after treatment
- fluid retention (edema)
- spotty darkening of the skin, particularly on the face
- rash
- weight changes
- depression
- intolerance to contact lenses
- nervousness
- dizziness
- loss of scalp hair

Call your healthcare provider right away if you get any of the symptoms listed below. They may be signs of a serious problem:

- sharp chest pain, coughing blood, or sudden shortness of breath (possible clot in the lung)
- pain in the calf (back of lower leg; possible clot in the leg)
- crushing chest pain or heaviness in the chest (possible heart attack)
- sudden severe headache or vomiting, dizziness or fainting, problems with vision or speech, weakness, or numbness in an arm or leg (possible stroke)
- sudden partial or complete loss of vision (possible clot in the eye)
- yellowing of the skin or whites of the eyes (jaundice), especially with fever, tiredness, loss of appetite, dark colored urine, or light colored bowel movements (possible liver problems)
- severe pain, swelling, or tenderness in the abdomen (gallbladder or liver problems)
- sudden fever (usually 102°F or more), vomiting, diarrhea, dizziness, fainting, or a sunburn-like rash on the face or body (very rarely, toxic shock syndrome)
- breast lumps (possible breast cancer or benign breast disease)
- irregular vaginal bleeding or spotting that happens in more than one menstrual cycle or lasts for more than a few days
- urgent, frequent, burning and/or painful urination, and you cannot locate the ring in the vagina (rarely, accidental placement of NuvaRing® into the urinary bladder)
- swelling (edema) of your fingers or ankles
- difficulty in sleeping, weakness, lack of energy, fatigue, or a change in mood (possible severe depression)

How effective is NuvaRing®?

If NuvaRing® is used according to the directions, your chance of getting pregnant is about 1 to 2% a year. This means that, for every 100 women who use NuvaRing® for a year, one or two will become pregnant. Your chance of getting pregnant increases if NuvaRing® is not used exactly according to the directions.

By comparison, the chances of getting pregnant in the first year of typical use (not always following directions exactly) of other methods of birth control are as follows:

No birth control method:	85%
Spermicides alone:	26%
Periodic abstinence methods (calendar, ovulation, thermometer):	25%
Withdrawal:	19%
Cervical Cap with spermicides:	20 to 40%
Vaginal sponge:	20 to 40%
Diaphragm with spermicides:	20%
Condom alone (male):	14%
Condom alone (female):	21%
Oral contraceptives:	5%
IUD:	less than 1 to 2%
Implants:	less than 1%
Injection:	less than 1%
Sterilization:	less than 1%

Other Information

- Store NuvaRing[®] at room temperature, 25°C (77°F). Temperatures can be from 59–86°F (15–30°C). Avoid direct sunlight or storing above 86°F (30°C).
- Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use NuvaRing[®] for a condition for which it was not prescribed. Do not give NuvaRing[®] to anyone else who may want to use it.
- Place the used ring in the reclosable foil pouch and properly dispose of it in a waste receptacle out of the reach of children and pets.

This leaflet summarizes the most important information about NuvaRing[®]. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NuvaRing[®] that is written for health professionals.

1-877-NUVARING



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