

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

# Pr **NUVARING**<sup>®</sup>

etonogestrel/ethinyl estradiol slow release vaginal ring

#### CONTRACEPTIVE VAGINAL RING

This leaflet is part III of a three-part "Product Monograph" published when NuvaRing was approved for sale in Canada, and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NuvaRing. Contact your doctor or pharmacist if you have any questions about the use of this product.

**READ THIS PAMPHLET CAREFULLY BEFORE YOU START USING NUVARING.**

#### ABOUT THIS MEDICATION

##### What the medication is used for:

NuvaRing (NEW-vah-ring) is a flexible contraceptive vaginal ring used to prevent pregnancy.

##### What it does:

Since NuvaRing releases two different types of hormones, an estrogen and a progestin, it is called a combination hormonal contraceptive (CHC). NuvaRing delivers 120 mcg of the progestin etonogestrel and 15 mcg/day of the estrogen, ethinyl estradiol. NuvaRing works by releasing a steady dose of progestin and estrogen into the body. The ring is inserted into the vagina and left in place for 3 weeks in a row.

Like other combination hormonal contraceptives, NuvaRing works in two ways:

1. By inhibiting the monthly release of an egg by the ovaries.
2. By changing the mucus produced by the cervix. This slows the movement of the sperm through the mucus into the uterus further reducing the chance of fertilization.

NuvaRing has been shown to be highly effective in preventing pregnancy when used as prescribed.

When used according to directions, NuvaRing is 98 to 99% effective at preventing pregnancy. This means that, for every 100 women who use NuvaRing for a year, about one or two will become pregnant. Your chance of getting pregnant increases if NuvaRing is not used exactly according to the directions.

#### Other ways to prevent pregnancy

Other methods of birth control are available to you.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

Reported Pregnancies per 100 Women per Year

Combination pill	less than 1 to 2
Contraceptive vaginal ring	between 1 and 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how consistently and/or correctly they use each method. (This does not apply to IUDs since they are implanted in the uterus). When used as directed, users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

Hormonal contraceptives (such as NuvaRing) have important advantages over other methods of birth control. They also have certain risks that other methods do not. Your doctor is the best person to explain the consequences of any possible risks.

#### **Non-contraceptive benefits of hormonal contraceptives**

Several health advantages have been linked to the use of hormonal contraceptives.

- Reduction in the incidence of cancer of the uterus and ovaries.
- Reduction in the likelihood of developing benign (non-cancerous) breast disease and ovarian cysts.

- Less menstrual blood loss and more regular cycles. The risk of developing iron-deficiency anemia is thus reduced.
- There may be a decrease in painful menstruation and premenstrual syndrome (PMS).
- Acne, excessive hair growth and male-hormone-related disorders also may be improved.
- Ectopic (tubal) pregnancy may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.

**When it should not be used:**

Hormonal contraceptives are not suitable for every woman. You should not use combination hormonal contraceptives (including NuvaRing) if you have or have had any of the following conditions:

- unusual vaginal bleeding that has not yet been diagnosed
- blood clots in the legs, lungs, eyes, or elsewhere. For additional information, see section "RISKS OF USING HORMONAL CONTRACEPTIVES – Circulatory disorders".
- a stroke, heart attack, chest pain (angina pectoris) or other blood circulatory disorders in the brain
- known or suspected cancer of the breast or sex organs
- liver tumour associated with the use of the pill or other estrogen-containing products
- jaundice (yellowing of the eyes or skin), liver disease or liver tumour
- cancers which are caused by or enhanced by estrogen
- eye diseases, eye lesions or defects or loss of vision
- allergic reactions or hypersensitivity to the hormones found in the contraceptives or to any of the other components found in the contraceptive
- if you are pregnant or think you might be pregnant

**What the medicinal ingredient is:**

NuvaRing contains two female hormones: etonogestrel (a progestin) and ethinyl estradiol (an estrogen).

**What the important nonmedicinal ingredients are:**

NuvaRing also contains ethylene vinylacetate copolymers and magnesium stearate. NuvaRing does not contain any latex.

**What dosage forms it comes in:**

Slow-release vaginal ring – 11.4 mg etonogestrel/2.6 mg ethinyl estradiol to deliver 120 mcg etonogestrel /15 mcg ethinyl estradiol per day.

NuvaRing is available in boxes of 1 sachet and 3 sachets.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in birth control pill users over 35 years of age. Women should be counselled not to smoke.

Women who are obese are at particularly high risk of blood clots.

**NuvaRing (as with other hormonal contraceptives) DOES NOT PROTECT against HIV infection (AIDS) and other Sexually Transmitted Infections (STIs). For protection against STIs, it is advisable to use latex or polyurethane condoms while using NuvaRing.**

**BEFORE you use NuvaRing talk to your doctor or pharmacist if:**

- you are taking any other prescription or nonprescription drugs as these may interfere with the actions of NuvaRing
- you are or will be having major surgery
- you have breast conditions
- you have a family history of breast cancer
- you have breast disorders including pain, discharge from the nipples, thickenings, or lumps
- you have a family history of circulatory disorders including blood clots, heart attacks or strokes
- you have diabetes
- you have high blood pressure
- you have abnormal levels of fats in the bloodstream (high cholesterol or triglycerides)
- you are a cigarette smoker
- you have migraine headaches
- you have heart or kidney disease
- you have a history of seizures or epilepsy
- you have a history of mental depression
- you have fibroid tumours of the uterus
- you have gallbladder or pancreatic disease
- you have plans for forthcoming surgery
- you have a history of jaundice or other liver disease

Your doctor can advise you if you have any conditions that would pose a risk to you. The use of combination hormonal contraceptives (including NuvaRing) should always be supervised by your doctor, with regular follow up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year. Use NuvaRing only on the advice of your doctor and carefully follow all directions given to you. Use NuvaRing exactly as prescribed or you could become pregnant.

If you see another doctor, inform him or her that you are using NuvaRing.

NuvaRing may not be suitable for women with conditions that make the vagina more susceptible to vaginal irritation or ulceration. In some cases, vaginal (fibrous) tissue may grow over the ring, necessitating removal by a doctor.

Pregnancy is almost always more risky than using combination hormonal contraceptives. However, this risk with hormonal contraceptives can be higher if you are over 35 and you smoke.

If you and your doctor decide that, for you, the benefits of NuvaRing outweigh the risks, you should be aware of the following:

## **RISKS OF USING HORMONAL CONTRACEPTIVES**

Specific studies with vaginal administration of contraceptive hormones (as in NuvaRing) are limited. The information given below was obtained in studies with oral contraceptives (the Pill) and it may also apply to NuvaRing.

### **Circulatory disorders (including blood clot in legs, lungs, heart, eyes or brain)**

Blood clots can develop whether or not you are using hormones for contraception. They can also happen if you are pregnant. The risk is higher in users of combined oral contraceptives than in non-users, but it is not as high as the risk during pregnancy.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

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

If you have to undergo an operation, are bedridden for some time, or you are not supposed to walk (for example, when you have your leg or legs in plaster, or a bandage is put on to treat varicose veins), the risk of having a blood clot may be temporarily higher. In women who use contraceptive hormones, the risk may be yet higher. In such a case, ask your doctor well in advance about what you should do. Your doctor may tell you to stop using your hormonal contraception several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start using NuvaRing again after you are back on your feet.

If you notice possible signs of a blood clot, stop using NuvaRing and consult your doctor immediately (**see the symptoms in section 'Side Effects and What to do About Them'**).

## **Hormonal Contraceptives and Cancer**

### **Breast cancer**

Breast cancer has been found slightly more often in women that take the Pill than in women of the same age who do not take the Pill. It is not known whether the increased risk of breast cancer is caused by the use of a hormonal contraceptive. It may be that the women taking such a hormonal contraceptive were examined more often, so that the breast cancer is noticed earlier.

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include, onset of menstrual periods before age 12 years, never having children, having your first full-term pregnancy after the age of 30 years, never having breast fed a child, and daily alcohol consumption.

You should notify your doctor if you notice any breast lumps. You should also discuss breast self-examination with your doctor. A yearly breast examination by a health care professional is recommended for all women. You should also tell your doctor if a close relative has or ever had breast cancer (see Warnings & Precautions).

### **Cervical cancer**

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

Chronic infection with the Human Papilloma Virus (HPV) is believed to be the most important risk factor for cervical cancer. In women who use combined oral contraceptives for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the Pill itself but may be related to sexual behavior and other factors.

### **Liver tumours**

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you experience severe pain or a lump in the abdomen.

### **Gallbladder disease**

Users of hormonal contraceptives have a greater risk of developing gallbladder disease requiring surgery within the first year of use. The risk may double after four or five years of use.

### **Use in pregnancy**

Hormonal contraceptives should not be taken by pregnant women. There is no evidence, however, that the Pill can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

### **Use while breast feeding**

The hormones in contraceptives are known to appear in breast milk. These hormones may decrease the flow of breast milk if hormonal contraceptives are not resumed until nursing is established. Some of the medicine may pass through the milk to the baby and could cause yellowing of the skin (jaundice) and breast enlargement.

### **Pregnancy after stopping NuvaRing**

A woman's menstrual period may be delayed after stopping hormonal contraceptives. There is no evidence that the use of the contraceptive vaginal ring leads to a decrease in fertility. It is wise to delay starting a pregnancy for at least one menstrual period after stopping hormonal contraceptives, so that way the pregnancy can be more accurately dated. Your doctor can recommend a different (non-hormonal) method of contraception during this time.

### **Irregular Bleeding**

During the use of NuvaRing, in some women, unexpected vaginal bleeding (spotting or breakthrough bleeding) between periods may occur. You may need to use sanitary protection, but continue to use the ring as normal. If the irregular bleeding continues, becomes heavy or starts again, tell your doctor.

### **Ring Disconnection**

Very rarely NuvaRing may break. A broken ring is unlikely to cause an overdose because the ring will not release a higher amount of contraceptive hormones. If NuvaRing breaks, expulsion is more likely to occur (see 'What Should I do if NuvaRing disconnects?'). Therefore, if you notice that your NuvaRing has broken, discard that ring and replace it with a new ring as soon as possible.

### **Risk to the Partner**

The effects of hormones released by NuvaRing on male partners during sexual intercourse have not been studied.

During market use, partner penis discomfort (e.g., pain, rash, bruises and abrasions), has been reported.

## **INTERACTIONS WITH THIS MEDICATION**

Certain drugs may interact with hormonal contraceptives (including NuvaRing) and prevent NuvaRing from working properly. This can make hormonal contraceptives less effective in preventing pregnancy or cause unexpected bleeding (spotting or breakthrough bleeding). Hormonal contraceptives may also interfere with the working of other drugs.

Please inform your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also, tell any other doctor or dentist who prescribes another drug (or the dispensing pharmacist) that you use NuvaRing. They can tell you if you need to use an additional method of contraception and if so, for how long.

Drugs that may interact with NuvaRing include:

- drugs used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampicin, rifabutin) and HIV infections (e.g. ritonavir)
- antibiotics (e.g. penicillins, tetracyclines, metronidazole) for infectious diseases
- antifungals (e.g. griseofulvin)
- anti-coagulants (blood thinners)
- the herbal remedy, St. John's Wort
- antihypertensive drugs (for high blood pressure)
- antidiabetic drugs and insulin (for diabetes)
- prednisone
- sedatives and hypnotics (e.g. benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- antacids
- other drugs such as phenylbutazone, antihistamines, analgesics, antimigraine preparations, or Vitamin E
- cyclosporine
- anti-epileptic drugs (lamotrigine)
- Vitamin B12

### **Can I use tampons when using NuvaRing?**

The blood levels of the hormones released by NuvaRing were not changed when women used tampons along with NuvaRing. It is unknown how this affects the safety and the pregnancy protection 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?**

The blood levels of the hormones released by NuvaRing were not changed when women used vaginal, water-based spermicides (nonoxynol or N-9 products) along with NuvaRing.

The blood levels of the hormones released by NuvaRing were increased when women used either an oil-based or water-based vaginal medication (miconazole nitrate) for a yeast infection while NuvaRing was in place. Therefore, this may also happen with other yeast infection medications. The clinical relevance of this increase is

unknown. It is unknown how long-term use of spermicide or yeast infection medication with NuvaRing affects the safety and the pregnancy protection of NuvaRing.

## PROPER USE OF THIS MEDICATION

### **If you decide to use hormonal contraceptives**

If you and your doctor decide that, for you, the benefits of hormonal contraceptives outweigh the risks, you should be aware of the following:

1. Your doctor will advise you of the appropriate time to start the use of hormonal contraceptives after childbirth, miscarriage, or therapeutic abortion.
2. There is no need to stop taking hormonal contraceptives for a rest period.

If you want more information about contraceptive vaginal rings, ask your doctor or pharmacist.

### **Usual dose:**

NuvaRing is designed to be a once-a-month contraceptive regimen. The ring has to be inserted in your vagina. You can verify the presence of NuvaRing yourself, whenever you wish. After the ring is inserted, it releases a continuous low dose of hormones into your body. The ring stays in place for 3 weeks and then is removed for a one week ring free period. It is not necessary or recommended to remove NuvaRing during intercourse.

## READ THESE DIRECTIONS CAREFULLY

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.

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.

You should not use a NuvaRing if it was dispensed to you more than 4 months before or if the expiry date has passed. The dispensing date and expiry date are both shown on the carton and sachet.

Do not use the ring if you notice a colour change in the ring or any visible signs of deterioration.

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

### **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 within the first five days of your cycle. (i.e. Day 1-5 of the menstrual bleeding). Make sure you also use an extra method of birth control (barrier method), such as male condoms or spermicides during the first seven days of NuvaRing use in the first cycle.

#### If you are switching from a combined hormonal contraceptive containing both progestin and estrogen)

Switch from your previous combined hormonal contraceptive on any day, but at the latest on the day you would have started a new cycle, 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 switching from a progestin-only contraceptive (mini-pill, implant, injection, or from a progestagen-releasing intra-uterine system {IUS})

- When switching from a mini-pill, you can stop using the pill on any day of the month and switch to NuvaRing. Insert NuvaRing on the day immediately after your last pill.
- When switching from an implant, progestin-containing IUS or injectable contraceptive, start using NuvaRing on the same day you have your implant or IUS removed or on the day your next injection is due.

When you are switching from a progestin-only contraceptive, use an extra method of birth control, such as condoms and/or spermicide, for the first seven days after inserting NuvaRing.

### **“Use after pregnancy, miscarriage or abortion”**

Talk to your doctor about using NuvaRing following an abortion, miscarriage or childbirth or under any other circumstances that are not listed in this Consumer Information.

### **How do I insert NuvaRing?**

1. 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 a position that is most comfortable for you (e.g., Figure 1).

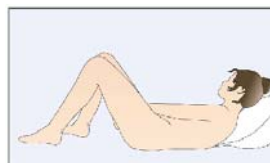
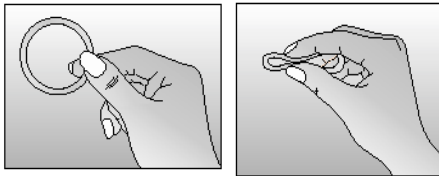




Figure 1: Positions for NuvaRing insertion

2. Press the sides of NuvaRing together between your thumb and index finger (Figure 2) and gently push the folded ring into your vagina (Figure 3). The exact position of NuvaRing in the vagina is not important for it to work.



Figures 2: Holding NuvaRing and pressing the sides together.



Figure 3: Inserting 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, use your finger to gently push NuvaRing further into your vagina. **There is no danger of NuvaRing being pushed too far up in the vagina or getting lost.**

3. Once inserted, keep NuvaRing in place for three weeks in a row.

#### How do I remove 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. For example, when NuvaRing is inserted on a Sunday at about 10:00 PM, the ring should be removed on the Sunday three weeks later at about 10:00 PM.

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).



Figure 4

2. 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. Do not throw it in the toilet.

If you are unable to remove NuvaRing, please contact your healthcare provider.

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.**

#### When do I insert a new ring?

After a one-week ring-free break, insert a new ring on the same day, at the same time of the week as it was removed in the last cycle. For example, if NuvaRing was removed on a Sunday at about 10:00 PM, after the one-week break you should insert a new ring on a Sunday at about 10:00 PM.

#### If NuvaRing is in your vagina too long:

If NuvaRing has been left in your vagina for an extra week or less (up to four weeks total), 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 total, there is a possibility that you could become pregnant. You must rule out pregnancy before inserting a new NuvaRing. You must use an extra method of birth control, such as condoms and/or spermicide, until the new NuvaRing has been in place for seven days in a row.

#### What should I do if NuvaRing disconnects?

On rare occasions, NuvaRing may disconnect at the weld joint during use. Since the ring's core is solid its contents will remain intact and release of hormones will not be significantly affected. If NuvaRing does disconnect, expulsion (slipping out) is 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.

#### How to change the NuvaRing start day to another day of the week

If you wish to change the day on which you start a new NuvaRing cycle to another day of the week, complete the current cycle, removing NuvaRing on the same day of the week as the one on which you started. During the ring-free period, a new start day may be selected by inserting the new NuvaRing on the first occurrence of the desired day. This will be your new Day 1. In no case should there be more than 7 consecutive ring-free days.

The shorter the ring-free interval, the higher the risk that you do not have a period from your previous cycle. However, spotting or bleeding may occur during the use of the next ring. This practice is for a one-time only change

and should not to be used as a standard dosing regimen, as there are no long-term safety data available on the continuous use of NuvaRing.

### **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 you had 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

### **Overdose:**

Overdosage of combination hormonal contraceptives may cause nausea, vomiting, vaginal bleeding, or other menstrual irregularities. Given the nature and design of NuvaRing it is unlikely that overdosage will occur. If NuvaRing is broken, it does not release a higher dose of hormones. There are no antidotes and further treatment should be symptomatic.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### **Missed Dose:**

#### **If NuvaRing slips out:**

NuvaRing can slip out of the vagina if it has not been inserted properly, or 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 should be re-inserted as soon as possible, and at the latest within three hours of expulsion (slipping out). If you have lost NuvaRing, you must insert a new NuvaRing and use it on the same schedule as you would have used the lost ring.
- If NuvaRing has been out of the vagina **for more than three hours during the 1<sup>st</sup> or 2<sup>nd</sup> week**, you may not be adequately protected from pregnancy. Re-insert the ring as soon as you remember and use an extra method of birth control, such as male condoms or spermicides, until the NuvaRing has been in place continuously for **seven days in a row**.

If NuvaRing slips out of the vagina for more than 3 hours during the 3<sup>rd</sup> week contraceptive efficacy may be reduced. Throw the ring away and choose one of the following two options:

1. Insert a new ring immediately. Note: 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 7 days from the time the previous ring was removed or expelled. Note: This option should only be chosen if the ring was used continuously for the preceding 7 days.

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

Women with conditions affecting the vagina, such as a prolapsed uterus, may be more likely to have NuvaRing slip out of the vagina.

#### **If the ring-free period is extended**

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. Contact your doctor immediately. The longer the ring-free interval, the higher the risk that you have become pregnant

### **How well tolerated is NuvaRing?**

More than 2,100 women were questioned in a survey of their experiences using NuvaRing for several months.

Nearly all of the women found NuvaRing easy to insert (96%) and remove (98%). Most women did not feel NuvaRing once it was in place and 83% of women said they never or rarely felt NuvaRing during intercourse. Similarly, 68% of women said their partners never or rarely felt the ring during intercourse, and 91% reported that their partner did not mind them using the ring.

Of the women who completed the study (approximately 1,500), 96% reported they were satisfied or very satisfied with NuvaRing (85% of all women surveyed were satisfied), and 90% reported they would recommend NuvaRing to others.

## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Combination hormonal contraceptives (including NuvaRing) are not suitable for every woman.

In a small number of women, serious side effects may occur. The most serious side effects of combined hormonal contraceptives include:

- circulatory disorders (including blood clots in legs, lungs, heart, eyes, or brain)
- breast cancer
- gall bladder disease or liver tumours

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 Warnings and Precautions). Do not forget about the items related to your immediate family.

Be alert for the following symptoms and signs of serious adverse effects. Call your doctor immediately if they occur:

- sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.
- pain and/or swelling in the calf. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain or heaviness. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.
- sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.
- severe pain or lump in the abdomen. These symptoms could indicate a possible tumour of the liver.
- severe depression
- yellowing of the skin (jaundice)
- unusual swelling of the extremities
- breast lumps.

With all hormonal contraceptives, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to use NuvaRing as normal. Irregular vaginal bleeding usually stops once your body has adjusted (usually after about 3 cycles). If it continues, becomes heavy or starts again, tell your doctor.

Users of NuvaRing have reported the following side effects:

- headache;
- vaginal discomfort (e.g. vaginal secretion, infection of the vagina );
- weight increase;
- nausea;
- breast pain;
- mood changes (e.g. depressive moods and emotional lability);
- painful menstruation;
- acne;
- decreased libido;
- abdominal pain;
- migraine;
- expulsion of the ring, problems during intercourse and feeling of the ring.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In rare cases the following undesirable effects were reported during use of NuvaRing: itching in the genital area, rash, inflammation of the cervix, urinary tract infection, bladder infection, dizziness, anxiety, diarrhea and vomiting, breast tumour formation, back pain, enlarged abdomen and fatigue.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Talk with your doctor or pharmacist		Remove the ring and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Uncommon</b>			
sharp pain in chest, coughing blood, or sudden shortness of breath/blood clot in the lung			√
pain in the calf/blood clot in the leg			√
crushing chest pain or heaviness/ heart attack			√
sudden severe or worsening headache or vomiting, dizziness or fainting, disturbance of vision or speech, or weakness or numbness in an arm or leg/stroke			√
sudden partial or complete loss of vision or double vision/ blood clot in the eye			√
severe pain or lump in the abdomen/ liver tumour			√
severe depression			√
yellowing of the skin/ jaundice			√
unusual swelling of the extremities			√
breast lumps/ breast cancer		√	√
urinary urgency, frequency, burning and/or painful urination, and can not locate the ring in the vagina/ inadvertent insertion of NuvaRing into the urinary bladder		√	√

This is not a complete list of side effects. For any unexpected effects while taking NuvaRing, contact your doctor or pharmacist.

## HOW TO STORE IT

Store NuvaRing at room temperature (2-30°C) and avoid direct sunlight.

Keep out of reach of children and pets.

## REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701D  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Merck Canada Inc. at: 1-800-463-5442

This leaflet was prepared by Merck Canada Inc.

Last revised: February 7, 2011

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