Etonogestrel/Ethinyl Estradiol Vaginal Ring

The NuvaRing® is a hormonal contraceptive that works in a similar way to the oral birth control pill and the Ortho Evra birth control patch. The NuvaRing, however, is a flexible, soft, two-inch ring that is worn in the vagina for three weeks and removed for one week. During the fourth week, which is NuvaRing-free, the woman will have a menstrual period—like those using the pill or the patch. After the ring-free week, a new NuvaRing may be inserted and the cycle begins again.

Patients insert the NuvaRing while lying down, standing or squatting. They simply press the sides together, push it gently into the vagina, and position it deep inside where the vaginal muscles will hold it into place. NuvaRing users do not feel the ring when it is correctly in place, and it should not be affected by exercise or intercourse.

The NuvaRing is manufactured by Organon USA (partnered with Organon in Oss, the Netherlands). Organon is the largest of three pharmaceutical companies owned internationally by Akzo Nobel in the Netherlands. Akzo Nobel operates in more than 80 companies with about 66,000 employees.

How hormonal contraceptives work

Hormonal contraceptives release estrogen and progestin hormones into the body, preventing the ovaries from releasing eggs and thinning the uterine lining to prevent implantation of a fertilized egg. Additionally, these hormones thicken cervical mucus, thus preventing sperm from entering the uterus.

History of the NuvaRing

The NuvaRing was approved by the Food and Drug Administration (FDA) in October 2001, just one month before the Ortho Evra birth control patch was approved. The NuvaRing is the first hormonal vaginal contraceptive ring on the market.

Studies conducted by the FDA during the approval process say that this form of birth control is 99 percent effective.

Organon, Inc.—a pharmaceutical company headquartered in West Orange, NJ, and NV Organon, the Netherlands—developed the NuvaRing. An FDA Talk Paper (http://www.fda.gov/ohrms/dockets/ac/01briefs/01BRIEF411.pdf) references two trials including more than 2,300 women in the U.S., Europe, Canada and Israel. The NuvaRing was evaluated during these trials for safety, effectiveness and acceptability among these women.

How the NuvaRing works

The NuvaRing releases etonogestrel (a progestin hormone) and ethinyl estradiol (an estrogen hormone) through the vaginal wall directly into the blood stream to prevent pregnancy.

A 2005 report from Organon USA said that data showed that estrogen exposure when using the NuvaRing was “significantly lower than that achieved with the transdermal patch and oral contraceptive.”

Further details of the report follow:

“The pharmacokinetic comparison of ethinyl estradiol (EE) released from the transdermal patch (Ortho Evra®3), an oral contraceptive (Microgynon®37) and NuvaRing® demonstrates that estrogen exposure with NuvaRing® was 3.4 times lower than observed with the patch and 2.1 times lower than observed with the oral contraceptive. Both differences were statistically significant. Such a three-way comparison of different hormonal contraceptives with different routes of administration has not been previously reported.”

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Health risks

Like the risks of other hormonal contraceptives like the pill and the Ortho Evra patch, the NuvaRing increases the possibility of blood clots, stroke and heart attack in patients. The label also carries a bold warning about the dangers of cigarette smoking while using this drug. Smoking can seriously increase the risk of cardiovascular complications among patients using hormonal contraceptives.

In 2005, the FDA changed the labeling for the NuvaRing, adding warnings of bleeding irregularities, and stating that the drug product should not be used in women who have valvular heart disease with thrombogenic complications. The changes also included the additions of precautions including tampon use, Toxic Shock Syndrome (TSS), drug interactions and more (http://www.fda.gov/medwatch/safety/2005/jul05.htm).

Adverse effects of the NuvaRing

Many risks and side effects have been reportedly associated with the NuvaRing and other hormonal birth control.

Serious side effects:

See a doctor immediately you experience any of the following symptoms!

- Chest pain or breathing difficulty.
- Coughing blood.
- Severe headaches, weakness or numbness.
- Pain in the arms or legs (especially calf or thigh).
- Vision loss or flashing lights.
- Severe abdominal pain.
- Jaundice (yellowing of skin or eyes).
- Breast lumps.
- Drastic change in mood.
- Severe fatigue.
- Sleeplessness.

Some of these symptoms may be warnings of blood clot (thrombosis), stroke, heart attack, pulmonary embolism or other serious medical problems. Go to the emergency room or call your doctor immediately if you are experiencing the above symptoms!
Serious risks:

Blood clot (thrombosis)
Heart attack (myocardial infarction)
Stroke
Gallbladder disease
Elevated blood pressure
Pulmonary embolism
Cerebral hemorrhage
Ocular lesions
Hepatic adenomas (benign liver tumors)

Common side effects:

Mild headaches
Nausea
Moodiness
Weight gain
Increased vaginal discharge
Vaginal infections/irritation
Sinusitis
Upper respiratory infection

Other possible side effects:

Depression
Vomiting
Spotting/mid-cycle bleeding
Appetite change
Breast tenderness
Rash
Intolerance to contact lenses
Cramps and bloating

The NuvaRing Web site includes the following warning:

IMPORTANT SAFETY INFORMATION NuvaRing® does not protect against HIV infection and other sexually transmitted diseases. The use of combination oral contraceptives is associated with increased risks of several serious side effects, including blood clots, which may lead to stroke or heart attack. 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. Cigarette smoking increases the risk of serious cardiovascular side effects; women who use combination hormonal contraceptives are strongly advised not to smoke. For additional important information, please see NuvaRing® Prescribing Information.

Links

http://www.rxlist.com/cgi/generic4/nuvaring_wcp.htm
http://www.nuvaring.com/Consumer/index.asp
http://www.fda.gov/bsx/topics/ANSWERS/2001/ANS01107.html

See Also

1. Pregnancy & Female Reproduction Drugs: Overview
2. Blood Clots
3. Heart Attack Lawsuits
4. Heart Problems
5. Strokes

Who We Are

The Injury Board is a growing community of attorneys, media professionals, safety industry experts, and local activists committed to making a difference by helping families stay safe and avoid injury, and helping those who are injured get the assistance they need to move on with their lives after an accident. Learn More