Merck Launches NEXPLANON® (etonogestrel implant) 68 mg in the United States - A Long-Acting Reversible Hormonal Contraceptive Effective For Up to Three Years

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WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (known as MSD outside the United States and Canada) (NYSE: MRK) today announced that NEXPLANON® (etonogestrel implant) 68 mg, a long-acting, progestin-only single-rod hormonal contraceptive, is now available in the United States. NEXPLANON is approved by the FDA for the prevention of pregnancy in women for up to three years. NEXPLANON must be removed by the end of the third year and may be replaced by a new NEXPLANON, if continued contraceptive protection is desired.

About the size of a matchstick, NEXPLANON is made of a soft, flexible, medical polymer and is inserted just under the skin of a woman's upper arm in a minor surgical in-office procedure. All healthcare providers performing insertions and/or removals of NEXPLANON should receive instructions and training prior to inserting or removing the implant. Training on the insertion and removal of NEXPLANON is offered by Merck.

NEXPLANON is effective, when inserted correctly, with less than 1 pregnancy per 100 women who used NEXPLANON for 1 year. NEXPLANON may be less effective in women who are very overweight and in women who are taking medications that induce liver enzymes. NEXPLANON is a progestin-only contraceptive that does not contain estrogen. NEXPLANON does not depend on daily, weekly, monthly, or quarterly administration. Etonogestrel, the progestin in NEXPLANON, prevents pregnancy in three ways: inhibiting ovulation, thickening of the cervical mucus, and alterations in the endometrium.

“Merck is committed to providing women with a range of birth control options. We are excited to add NEXPLANON to Merck’s growing Women’s Health portfolio,” said Terrie Curran, senior vice president and general manager, Women’s Health at Merck.

NEXPLANON is indicated for use by women to prevent pregnancy. NEXPLANON is radiopaque, which means physicians can verify presence of the implant after insertion and can locate it prior to removal using two-dimensional X-ray, computed tomography (CT scan), ultrasound scanning (USS), or magnetic resonance imaging (MRI). After insertion and prior to removal, physicians should always verify the presence of the implant in the woman's arm by palpation. If the implant cannot be palpated, the physician can use one of the four available methods to verify presence of the implant. Until the presence of the implant has been verified, women using NEXPLANON should be advised to use a non-hormonal contraceptive method, such as condoms.

Removal of NEXPLANON can occur at any time during the three years at the request of the user. In clinical trials, pregnancies were observed to occur as early as seven to fourteen days after removal of NEXPLANON. If pregnancy is not desired after removal of NEXPLANON, another method of birth control must be started immediately.

Selected Safety Information about NEXPLANON

NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; or allergic reaction to any of the components of NEXPLANON.

NEXPLANON should be inserted subdermally so that it will be palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert NEXPLANON properly may go unnoticed unless it is palpated immediately after insertion. Undetected failure to insert the implant may lead to an unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

Complications related to insertion and removal procedures, such as pain, paresthesias, bleeding, hematoma, scarring, or infection, may occur. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. Deep insertions may lead to difficult localization of the implant and may also result in the need for a surgical procedure in an operating room in order to remove the implant.
After starting NEXPLANON, women are likely to have changes in their menstrual bleeding pattern. These may include changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, reports of changes in bleeding pattern were the most common reason for stopping treatment (11.1%). Women should be counseled regarding bleeding pattern changes that they may experience.

Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.

The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep vein thrombosis, retinal vein thrombosis, and pulmonary embolism). It is recommended that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed. There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using the non-radiopaque etonogestrel implant. NEXPLANON should be removed in the event of a thrombosis. Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. Rarely, surgery may be required.

Some studies suggest that the use of combination hormonal contraceptives might increase the incidence of breast cancer, and increase the risk of cervical cancer or intraepithelial neoplasia. Women with a family history of breast cancer or who develop breast nodules should be carefully monitored.

NEXPLANON should be removed if jaundice occurs.

The NEXPLANON implant should be removed if blood pressure rises significantly and becomes uncontrolled.

Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON.

Prediabetic and diabetic women using NEXPLANON should be carefully monitored.

Women with a history of depressed mood should be carefully observed. Consideration should be given to removing NEXPLANON in patients who become significantly depressed.

In clinical trials with the non-radiopaque etonogestrel implant (IMPLANON), the etonogestrel levels in blood decreased below sensitivity of the assay by one week after removal of the implant. In addition, pregnancies were observed to occur as early as 7 to 14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired.

Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention.

Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

The most common adverse reaction causing discontinuation of use of the implant in clinical trials was change in menstrual bleeding patterns, specifically irregular menses (11.1%). The most common adverse reactions (≥10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).

Drugs or herbal products that induce enzymes, including CYP3A4, that metabolize progestins may decrease the plasma concentrations of progestins and may decrease the effectiveness of NEXPLANON. In women on long-term treatment with hepatic enzyme inducing drugs, it is recommended to remove the implant and to advise a contraceptive method that is unaffected by the interacting drug. Significant changes (increase or decrease) in the plasma levels of progestin have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

CYP3A4 inhibitors, such as itraconazole or ketoconazole, may increase plasma concentrations of etonogestrel.

Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporin) or decrease (for example, lamotrigine).

**Rule out pregnancy before inserting NEXPLANON.**

Based on limited clinical data, NEXPLANON may be used during breastfeeding after the fourth postpartum week. Use of NEXPLANON before the fourth postpartum week has not been studied. Small amounts of etonogestrel are excreted in breast milk. The health of breast-fed infants whose mothers began using the non-radiopaque etonogestrel implant during the fourth to eighth week postpartum (n=38) was evaluated in a comparative study with infants of mothers using a non-hormonal IUD (n=33). They were breast-fed for a mean duration of 14 months and followed up to 36 months of age. No significant effects and no differences between the groups were observed on the physical and psychomotor development of these infants. No differences between groups in the production or quality of breast milk were detected.

Safety and efficacy of NEXPLANON have been established in women of reproductive age and are expected to be the same for postpubertal adolescents. However, no studies have been conducted in women less than 18 years of age. Use of this
The efficacy of NEXPLANON in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, NEXPLANON may be less effective in overweight women.

NEXPLANON does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results; the combined company’s plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck’s ability to accurately predict future market conditions; dependence on the effectiveness of Merck’s patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2010 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).


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