NEXPLANON®
(etonogestrel implant) 68 mg
Radiopaque

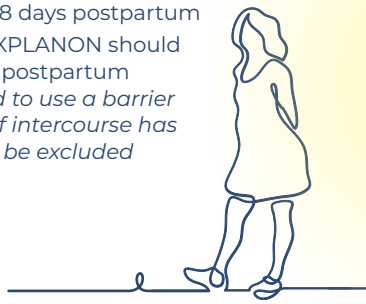
**NEXPLANON is indicated for prevention of pregnancy in women of reproductive potential for up to 5 years.**

# *Starting Contraception* With NEXPLANON

Timing of insertion depends on a patient's recent contraceptive history, as outlined below.

## If NEXPLANON is inserted during a different time than recommended, patients should be advised to use a barrier method until 7 days after insertion.

- If a patient has **no preceding hormonal contraceptive use in the past month,** NEXPLANON should be inserted between Day 1 (first day of menstrual bleeding) and Day 5 of the menstrual cycle, even if the woman is still bleeding
- If a patient is **switching from combination hormonal contraceptives,** NEXPLANON should preferably be inserted on the day after the last active tablet of the previous combined oral contraceptive or on the day of removal of the vaginal ring or transdermal patch. At the latest, NEXPLANON should be inserted on the day following the usual tablet-free, ring-free, patch-free, or placebo tablet interval of the previous combined hormonal contraceptive
- If the patient is **switching from a progestin-only contraceptive**, NEXPLANON should be inserted as follows:
  - For injectable contraceptives: The day the next injection is due
  - For minipills: Within 24 hours after taking the last tablet
  - For implants or intrauterine systems (IUS): The same day the previous implant or IUS is removed
- **Following an abortion or miscarriage**, NEXPLANON should be inserted
  - Within 5 days following a first-trimester abortion or miscarriage
  - Between 21 and 28 days following a second-trimester abortion or miscarriage
- **Postpartum** and **not breastfeeding**: NEXPLANON should be inserted between 21 and 28 days postpartum
- **Postpartum** and **breastfeeding**: NEXPLANON should not be inserted until after the fourth postpartum week. *The woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded*



## SELECTED SAFETY INFORMATION

**WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION and REMOVAL**

**Improper insertion of NEXPLANON increases the risk of complications.**

**Proper training prior to first use of NEXPLANON can minimize the risk of improper NEXPLANON insertion.**

**Because of the risk of complications due to improper insertion and removal NEXPLANON is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the NEXPLANON REMS.**

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

**Risk of Complications Due to Improper Insertion and Removal**

**Complications of insertion and removal**

- Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy.
- Insertion and removal-related complications that may occur include pain, paresthesia, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or intrafascial), neural or vascular injury may occur.
- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery; in these cases, endovascular or surgical procedures may be needed for removal.
- 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. If at any time the implant cannot be palpated, it should be localized, and removal is recommended. When an implant is removed, it is important to remove it in its entirety.
- 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.

**Broken or Bent Implants**

- Cases of breakage or bending of implants while inserted within a patient's arm have been reported. Cases of migration of a broken implant fragment within the arm have also occurred. These cases may be related to external forces, e.g., manipulation of the implant or contact sports. The release rate of etonogestrel may be slightly increased in a broken or bent implant, based on in vitro data.

**NEXPLANON REMS**

- NEXPLANON is only available through a restricted program under a REMS called NEXPLANON REMS because of the risk of complications due to improper insertion and removal.

  Notable requirements of the NEXPLANON REMS include the following:
  - Healthcare providers must be certified with the program by enrolling and completing training on the proper insertion and removal of NEXPLANON prior to first use.
  - Pharmacies must be certified with the program and must only dispense NEXPLANON to certified healthcare providers who dispense NEXPLANON for insertion.

**Selected Safety Information continued on next page**

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**NEXPLANON is indicated for prevention of pregnancy in women of reproductive potential for up to 5 years.**

**Up to 5 years of** pregnancy prevention[a]

Women of varying BMIs were included in the extended use study (years 4 and 5)

**NEXPLANON is >99% effective***

**Reversible** contraception if her plans change

*In the 3-year studies (Pearl Index: 0.38 pregnancies per 100 women-years of use), women weighing more than 130% of their ideal body weight were excluded.

In the extended use study (Pearl Index: 0.0 pregnancies per 100 women-years of use), the mean BMI was 29.4 kg/m$^2$ (17.2-64.3 kg/m$^2$), and the mean weight was 78.7 kg (40.8-180.8 kg).

[a]NEXPLANON must be removed by the end of the fifth year and may be replaced by another NEXPLANON at the time of removal, if continued contraceptive protection is desired.

BMI = body mass index.

## SELECTED SAFETY INFORMATION (*continued*)

### NEXPLANON REMS (*continued*)

- Wholesalers and distributors must be registered with the program and must only distribute to certified pharmacies and certified healthcare providers.

Further information is available at www.NEXPLANONREMS.com and 1-833-697-7367.

### Changes in Menstrual Bleeding Patterns

- After starting NEXPLANON, women are likely to have changes in their menstrual bleeding patterns, which can 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, the most common reason for discontinuation was changes in bleeding patterns (11.1%).

### Ectopic Pregnancies

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

### Thrombotic and Other Vascular Events

- There have been postmarketing reports of serious arterial thrombotic and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. Assess women with known risk factors. NEXPLANON should be removed if thrombosis occurs.
- NEXPLANON should not be used prior to 21 days postpartum due to risk of thromboembolism.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence.
- In case of long-term immobilization, consider removing NEXPLANON.

### ADDITIONAL WARNINGS & PRECAUTIONS AND ADVERSE REACTIONS

- Remove NEXPLANON if jaundice occurs or blood pressure rises significantly and becomes uncontrolled.
- Monitor prediabetic and diabetic women using NEXPLANON.
- Observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.
- The most common adverse reactions (≥5%) reported in 3-year 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%). In a separate clinical trial to assess contraceptive efficacy and safety of NEXPLANON beyond 3 years, up to 5 years, a similar adverse reaction profile was observed as in Years 1 through 3. The most frequently reported adverse reaction >5% was intermenstrual bleeding (5.4%).

### DRUG INTERACTIONS AND USE IN SPECIFIC POPULATIONS

- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- **Rule out pregnancy before inserting NEXPLANON.**
- NEXPLANON does not protect against HIV or other STDs.

**Before prescribing NEXPLANON, please read the Prescribing Information, including Boxed Warning. The Patient Information also is available.**

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