Indications and clinical use:
PrNEXPLANON® (etonogestrel extended release subdermal implant) is indicated for the prevention of pregnancy for up to 3 years.

Pediatrics (<18 years of age): Safety and efficacy have been studied in women between 18 and 40 years. NEXPLANON® is not indicated for use before menarche. No clinical studies have been conducted in women less than 18 years of age; therefore, Health Canada has not authorized an indication for pediatric use.

Geriatrics (>65 years of age): This product has not been studied in women over 65 years of age and is not indicated in postmenopausal women. No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

Overweight women: NEXPLANON® may become less effective in overweight women over time, especially in the presence of other factors that decrease etonogestrel concentrations, such as concomitant use of hepatic enzyme inducers

Contraindications:
- Women with:
  - o Known or suspected pregnancy;
  - o Current or past history of thrombosis or thromboembolic disorders;
  - o Liver tumours, benign or malignant, or active liver disease;
  - o Undiagnosed abnormal genital bleeding;
  - o Known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past.

Most serious warnings and precautions:
Insertion and/or removal by a Healthcare Professional only: All Healthcare Professionals should receive instruction and training prior to performing insertion and/or removal of NEXPLANON®, and, where appropriate, request supervision prior to inserting or removing the implant.

Immediate action if not palpable: If at any time the implant is not palpable by the Healthcare Professional or the patient, NEXPLANON® should be localized as soon as possible and removed as soon as medically appropriate to manage the risks of migration. There have been post-marketing reports of implants located within the vessels of the arm and the pulmonary artery which may be related to deep insertions or intravascular insertion.

Protection against STIs: Women should be counselled that NEXPLANON® DOES NOT PROTECT against sexually transmitted infections (STIs) including HIV/AIDS. For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH NEXPLANON®.

Other relevant warnings and precautions:
- Complications of insertion and removal
- Changes in the menstrual bleeding pattern
- *In situ* broken or bent implant. The broken implant may move from the insertion site.
- Need for medical examination/consultation prior to the initiation or reinstitution of NEXPLANON®
- Reduced efficacy with concomitant medications
- Risk of carcinoma of the breast and reproductive organs
- Risk of elevated blood pressure
- Risk of thrombotic and other vascular events
- Carbohydrate and lipid metabolic effects
- Weight gain
- Fluid retention
- Risk of ectopic pregnancy
- Risk of ovarian cysts
- Liver disease
- Risk of gallbladder disease
- Effect on laboratory parameters
- Ophthalmologic considerations in contact lens wearers
- Peri-operative considerations
- Depressed mood
- Return to ovulation
- Chloasma
- Use in special populations (i.e., breast-feeding women)
- Other conditions reported during pregnancy and during sex steroid use not otherwise described

For more information:
Please consult the Product Monograph at https://www.organon.com/canada-en/wp-content/uploads/sites/5/2021/05/NEXPLANON-PM_E.pdf for important information relating to adverse reactions, drug interactions, and dosing information, which have not been discussed in this piece. The Product Monograph is also available through our medical department. Call us at 1-844-820-5468.

References: 1. NEXPLANON® Product Monograph. Organon Canada Inc. April 13, 2021. **2.** Data on file. **3.** Black A, Francoeur D, Rowe T, et al. Canadian Contraception Consensus. *JOGC* 2004;143:219-254.

Find a Healthcare Professional Trained to Insert NEXPLANON®

Insertion of NEXPLANON® should be performed under aseptic conditions and only by a qualified healthcare professional (HCP) who is familiar with the procedure.

Use the Clinic Finder to find an HCP trained to insert NEXPLANON®
https://cloud.mail.organon.ca/nexplanon-clinic-finder

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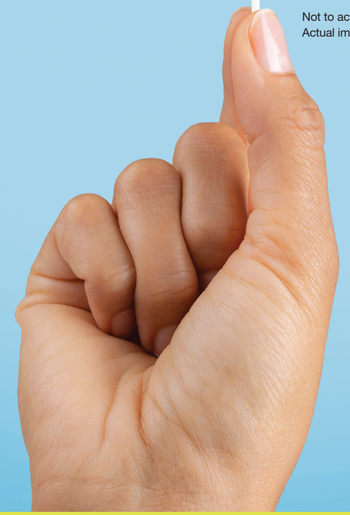
ORGANON

Nexplanon®
etonogestrel extended release subdermal implant

UP TO 3 YEARS OF PREGNANCY PREVENTION



Not to actual size.
Actual implant is 4cm in length.

NEXPLANON®: THE FIRST AND ONLY SINGLE-ROD, PROGESTIN-ONLY LARC THAT'S IMPLANTED IN THE ARM*[1,2]

NEXPLANON® is indicated for prevention of pregnancy for **up to 3 years**.[1]

NEXPLANON® does not protect against sexually transmitted infections (STIs) including HIV/AIDS. Counsel your patients that it is advisable to use latex or polyurethane condoms in combination with NEXPLANON® for protection against STIs.

LARC=long-acting reversible contraceptive.
* Comparative clinical significance is unknown.

ORGANON

NEXPLANON®: A **radiopaque** etonogestrel subdermal implant

Contraceptive efficacy and safety of NEXPLANON® was evaluated in 11 studies and over 900 women* using the non-radiopaque etonogestrel subdermal implant.

NEXPLANON®	IMPLANON®*
Radiopaque etonogestrel subdermal implant	***Non-radiopaque*** etonogestrel subdermal implant

* The contraceptive efficacy database provides data from 923 subjects. The safety assessment was based on 942 subjects.

IN A BIOEQUIVALENCE STUDY

NEXPLANON® and the non-radiopaque etonogestrel subdermal implant met comparative bioavailability standards[1]

- Comparative bioavailability of NEXPLANON® and the non-radiopaque implant was assessed in a multicenter, randomized, double-blind, parallel group bioequivalence study in healthy volunteers
- C_{max} and AUC parameters were determined from 2 days through 3 years after subdermal insertion of the implants
- NEXPLANON® and the non-radiopaque subdermal implant (IMPLANON®)* met comparative bioavailability standards with respect to rate and extent of etonogestrel absorption

AUC=area under the blood concentration versus time curve; C_{max}=maximum blood concentration.
* IMPLANON® is not available.

10+ years of experience worldwide

Zero on-treatment pregnancies occurred in clinical trials using the non-radiopaque implant (IMPLANON®)*

The Pearl Index was zero (95% CI: 0, 0.20)†

- Clinical trials of up to 3 years' duration involved 923 subjects with 1,832 women-years of exposure (or 23,883 of 28-day cycle equivalents) treated with the non-radiopaque etonogestrel implant*
- The clinical trials excluded women who:
  - Weighed more than 130% of their ideal body weight
  - Were chronically taking medications that induce liver enzymes

* IMPLANON® is not available.
† The Pearl Index is defined as the number of contraceptive failures per 100 women-years of use.[3]

Overall, annual, and cumulative Pearl Indices for etonogestrel subdermal implant*

PARAMETER	OVERALL		
Number of subjects (N)	923		
Pregnancies (n)	0		
Exposure in women-years	1,832		
28-day cycle equivalents	23,883		
Pearl Index (95% CI)	0 (0, 0.20)		
PARAMETER	**ANNUAL**		
	Year 1 (Day 1-365)	Year 2 (Day 366-730)	Year 3 (Day 731-1,095)
Number of subjects (N)	923	743	533
Pregnancies (n)	0	0	0
Exposure in women-years	834	658	264
28-day cycle equivalents	10,866	8,581	3,441
Pearl Index (95% CI)	0 (0, 0.49)	0 (0, 0.62)	0 (0, 1.57)
PARAMETER	**CUMULATIVE**		
Number of subjects (N)	923	923	923
Pregnancies (n)	0	0	0
Exposure in women-years	834	1,492	1,755
28-day cycle equivalents	10,866	19,447	22,888
Pearl Index (95% CI)	0 (0, 0.44)	0 (0, 0.25)	0 (0, 0.21)

Table adapted from the NEXPLANON® Product Monograph.
* Results presented in this table were acquired using a non-radiopaque implant.

In the subgroup of women who conceived within 14 days of implant removal (18-35 years of age at entry), 6 pregnancies during 20,648 cycles of use were reported. Two pregnancies occurred in each of Years 1, 2, and 3. Each conception was likely to have occurred shortly before or within 2 weeks after removal of the non-radiopaque etonogestrel implant. With these 6 pregnancies, the cumulative Pearl Index was 0.38 pregnancies per 100 women-years of use.

Reversible

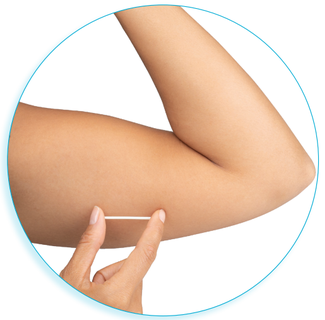
In clinical trials with the non-radiopaque etonogestrel implant (IMPLANON®):

Etonogestrel levels in blood decreased below sensitivity of the assay by one week post-implant removal

Pregnancies were observed to occur as early as **7 to 14 days after removal**

A woman should restart contraception immediately after removal of the implant if continued contraceptive protection is desired.

Implanted in the arm using an innovative, preloaded applicator[1]



(Applicator is not actual size)

NEXPLANON® is inserted subdermally at the inner side of the non-dominant upper arm.[1]

Refer to the NEXPLANON® Product Monograph for complete insertion information.

- NEXPLANON® should be inserted and/or removed by a healthcare professional (HCP) familiar with use of the implant. All HCPs should receive training prior to performing insertion and/or removal of NEXPLANON®, and, where appropriate, request supervision prior to inserting or removing the implant.
- If at any time the implant is not palpable, it should be localized and removed as soon as medically appropriate to manage the risks of migration. There have been post-marketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion.

Mean insertion time was <30 seconds

Out of 301 insertions of the NEXPLANON® implant in a clinical trial:

Mean insertion time was **27.9 ± 29.3** seconds (from the removal of the protection cap of the applicator until retraction of the needle from the arm)

99.7% of implants were **palpable post-insertion***

* 300 out of 301; the single non-palpable implant was not inserted according to the instructions.[1]