NEXPLANON®
(etonogestrel implant) 68 mg
Radiopaque

NEXPLANON REMS OVERVIEW

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of NEXPLANON outweigh the risk of complications due to improper insertion and removal. Organon's existing Clinical Training Program (CTP), a program designed to help ensure healthcare providers can safely insert and remove NEXPLANON with the proper techniques, will remain in place and be incorporated into the NEXPLANON REMS.

All healthcare providers who dispense NEXPLANON for insertion must become certified in the NEXPLANON REMS. You will no longer have access to NEXPLANON for insertion if you have not completed certification by 8/23/2026.

Visit the NEXPLANON REMS website at www.NEXPLANONREMS.com or use your phone to scan this QR code to get started.

What is REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the FDA can require for certain medications with serious safety concerns before or after drug approval to help ensure that the benefits of the medication outweigh its risks.[1,2]

The goal of the NEXPLANON REMS is to mitigate complications due to improper insertion and removal.

Objective: Healthcare providers who perform NEXPLANON procedures demonstrate proper insertion and removal techniques for NEXPLANON prior to first use.

NEXPLANON®
(etonogestrel implant) 68 mg
Radiopaque

Key Healthcare Provider Requirements for the NEXPLANON REMS

Active NEXPLANON-Trained Healthcare Providers

You fall into this category if you have previously completed the Clinical Training Program (CTP) for NEXPLANON and HAVE inserted or removed NEXPLANON in the past 3 years. You will not need to repeat the CTP for NEXPLANON.

To Become Certified:

1. Review the following:
   - Prescribing Information, including the Instructions for Use
   - Healthcare Provider Guide
2. Complete and submit the Healthcare Provider Knowledge Assessment and the Healthcare Provider Enrollment Form online at www.NEXPLANONREMS.com, or fax them to the REMS at 1-833-430-2807.

Inactive NEXPLANON-Trained Healthcare Providers *OR* New NEXPLANON Healthcare Providers

You fall into this category if you previously completed the Clinical Training Program (CTP) for NEXPLANON and HAVE NOT inserted or removed NEXPLANON in the past 3 years, OR you have never completed the CTP for NEXPLANON.

To Become Certified:

1. Review the following:
   - Prescribing Information, including the Instructions for Use
   - Healthcare Provider Guide
2. Complete and submit the Healthcare Provider Knowledge Assessment and the Healthcare Provider Enrollment Form online at www.NEXPLANONREMS.com, or fax them to the REMS at 1-833-430-2807.
3. Successfully complete Didactic Training.
4. Take the in-person practical training provided by Organon and successfully complete the Competency Checklist.

For any questions or assistance, contact the NEXPLANON REMS at 1-833-697-7367.

Potential insertion- and removal-related events (IRREs) must be reported immediately to the NEXPLANON REMS using the Insertion- and Removal-Related Events Documentation Form or by calling 1-833-NXP-REMS (1-833-697-7367).

You are encouraged to report all other adverse events of NEXPLANON to Organon at 1-844-674-3200 or the FDA at http://www.fda.gov/medwatch or 1-800-FDA-1088.

References: 1. Risk evaluation and mitigation strategies | REMS. US Food and Drug Administration. Updated May 20, 2025. Accessed September 10, 2025. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems **2.** REMS: FDA's application of statutory factors in determining when a REMS is necessary guidance for industry. US Food and Drug Administration. April 2019. Accessed September 10, 2025. https://www.fda.gov/media/100307/download

ORGANON