

WHAT IS MIUDELLA?

MIUDELLA[®] Intrauterine Copper Contraceptive (“MIUDELLA”) is indicated for the prevention of pregnancy for up to 3 years.

WHAT IS THE MIUDELLA REMS (RISK EVALUATION AND MITIGATION STRATEGY)?

Because of the risk of complications due to improper insertion of MIUDELLA, MIUDELLA is only available through a restricted distribution program required by the Food and Drug Administration (FDA) called the MIUDELLA REMS.

- **Healthcare providers** who dispense MIUDELLA for insertion are educated prior to first use.
- **Pharmacies** that dispense MIUDELLA must be certified in the REMS and only provide MIUDELLA to healthcare settings after verifying that the healthcare settings are certified in the REMS.
- **Healthcare settings** that dispense MIUDELLA must be certified in the REMS and only provide MIUDELLA to healthcare providers at their healthcare settings after verifying that the healthcare providers are certified in the REMS.

RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION

- There is a risk of complications due to improper insertion of MIUDELLA by untrained healthcare providers.
- The MIUDELLA IUS inserter design and instructions are different from other IUS systems and there are a few unique steps associated with proper insertion of MIUDELLA.
- Therefore, healthcare providers who dispense MIUDELLA for insertion must be certified in the REMS to ensure that they are educated on proper insertion.

HOW DOES A HEALTHCARE SETTING BECOME CERTIFIED?

NOTE: Before the healthcare setting can be certified, one or more healthcare providers certified to dispense MIUDELLA for insertion must be affiliated with the address.

Designate an **Authorized Representative** to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting.

The Authorized Representative must:

- Carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting.
- Review the **Healthcare Setting Guide**.
- Enroll in the REMS by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing MIUDELLA on the REMS requirements.
- Establish processes and procedures:
 - To verify that all healthcare providers who dispense MIUDELLA for insertion are certified and are affiliated with the healthcare setting are certified.
 - To maintain records of healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with the healthcare setting.
 - To monitor healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with the healthcare setting to identify providers with a two-year period of inactivity to ensure these healthcare providers maintain certification in the REMS before dispensing MIUDELLA for insertion.

WHAT ARE THE RESPONSIBILITIES OF A CERTIFIED HEALTHCARE SETTING?

Before dispensing, all healthcare setting staff must:

- Verify that the healthcare provider who is inserting MIUDELLA at the healthcare setting is certified through the processes and procedures established as a requirement of the REMS.

At all times, my healthcare setting must:

- Monitor healthcare providers who are certified to dispense MIUDELLA for insertion to identify providers with a two-year period of inactivity to ensure these healthcare providers maintain certification in the REMS before dispensing MIUDELLA for insertion through the processes and procedures established as a requirement of the REMS.
- Not distribute, transfer, loan, or sell MIUDELLA except to certified pharmacies and healthcare settings.
- Maintain records that all processes and procedures are in place and being followed.
- Maintain records of healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with your healthcare setting.
- Comply with audits carried out by Sebela Women's Health Inc. or a third party acting on behalf of Sebela Women's Health Inc. to ensure that REMS processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS.

HOW DOES A HEALTHCARE SETTING ORDER MIUDELLA?

- Some MIUDELLA prescriptions will be fulfilled by a specialty **pharmacy** that receives a MIUDELLA prescription for fulfillment. In this case, the certified pharmacy would ship MIUDELLA to the certified healthcare setting affiliated with the certified healthcare provider for an individual, named patient.
- Other MIUDELLA prescriptions may be fulfilled by a **healthcare setting** that orders MIUDELLA from its distributor or wholesaler. In this case, the certified healthcare setting will fulfill a prescription for use by a certified healthcare provider within its healthcare setting for an individual, named patient.

Questions? Call the REMS at 1-855-337-0772 Monday-Friday, 8:00 AM – 8:00 PM ET

Report adverse events to Organon LLC at 1-844-674-3200 or to the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

To review complete safety information about MIUDELLA, please refer to the Prescribing Information at www.MIUDELLAREMS.com.