Miudella® (copper intrauterine system) – New drug approval

- On February 24, 2025, the FDA approved Sebela Women's Health's Miudella (copper intrauterine system), **for prevention of pregnancy in females of reproductive potential for up to 3 years**.

- Miudella is a copper-containing intrauterine system (IUS).

- The efficacy of Miudella was established in a single-arm, open-label study in 1,601 generally healthy women aged 17 to 45 years who had Miudella successfully placed. The primary endpoint was the contraceptive efficacy through 3 years of use as measured by the Pearl Index (PI) in women 17 to 35 years of age. Women enrolled in the study provided 12,493 evaluable 28-day cycle equivalents in the first year and 27,115 evaluable cycles over the three-year treatment period.

    - The cumulative 3-year PI or pregnancy rate was 1.05 (95% CI: 0.66, 1.60).

- Miudella carries a boxed warning for risk of complications due to improper insertion.

    - Miudella is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Miudella REMS program.

- Miudella is contraindicated when one or more of the following conditions exist:

    - Pregnancy or suspicion of pregnancy
    - Congenital or acquired abnormalities of the uterus, including leiomyomas, resulting in distortion of the uterine cavity
    - Acute pelvic inflammatory disease
    - Postpartum endometritis or postabortal endometritis in the past 3 months
    - Known or suspected uterine or cervical malignancy
    - For use as post-coital contraception (emergency contraception)
    - Uterine bleeding of unknown etiology
    - Untreated acute cervicitis or vaginitis or other lower genital tract infection
    - Conditions associated with increased susceptibility to pelvic infections
    - Wilson's disease
    - A previously placed IUS that has not been removed
    - Hypersensitivity to any component of Miudella including to polypropylene, copper, nitinol, an alloy of nickel and titanium, or any of the trace elements present in the copper component of Miudella.

- Additional warnings and precautions for Miudella include risk of ectopic pregnancy; risks with intrauterine pregnancy; sepsis; pelvic infection; perforation; expulsion; Wilson's disease; bleeding pattern alterations; MRI safety information; and medical diathermy.

- The most common adverse reactions (≥ 5%) with Miudella use were heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post procedural hemorrhage, dyspareunia.

- Miudella is inserted at the fundus of the uterine cavity. Miudella must be removed or replaced after 3 years.

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- Sebela Women's Health's launch plans for Miudella are pending. Miudella will be available as a copper-containing sterile IUS preloaded in a single use inserter.