

**PATIENT INFORMATION**  
**Miudella®** (mye yoo de' lah)  
**(intrauterine copper contraceptive)**

**Miudella® does not protect against human immunodeficiency virus (HIV) or other sexually transmitted infections (STIs).**

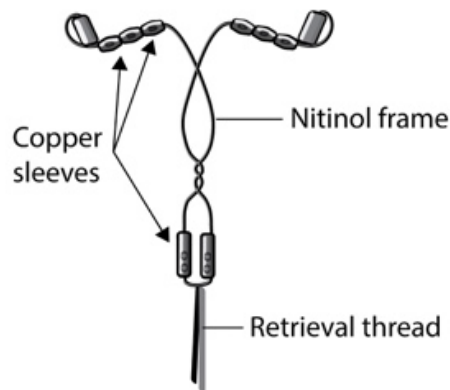
Read this Patient Information carefully before you decide if Miudella is right for you. This information does not take the place of talking with your health care provider (HCP). If you have any questions about Miudella, ask your health care provider. You also should learn about other birth control methods to choose the one that is best for you.

**What is Miudella?**

- Miudella is a low-dose copper-releasing intrauterine system (IUS) that is placed in your uterus by your health care provider to prevent pregnancy for up to 3 years.
- Miudella can be removed by your health care provider at any time.
- Miudella can be used whether or not you have previously given birth.

Miudella is a small, flexible, hormone-free intrauterine system with copper attached to a flexible wire frame that allows it to fit different uterus shapes and sizes. The wire frame is made of a material used in many medical products.

Miudella has a thin, soft retrieval thread attached to its base. Once Miudella is placed in your uterus, the thread ends extend into the vagina and can be felt. However, unlike a tampon string, the thread ends do not extend outside of your body.



**Miudella is small and flexible**

**What if I need birth control for more than 3 years?**

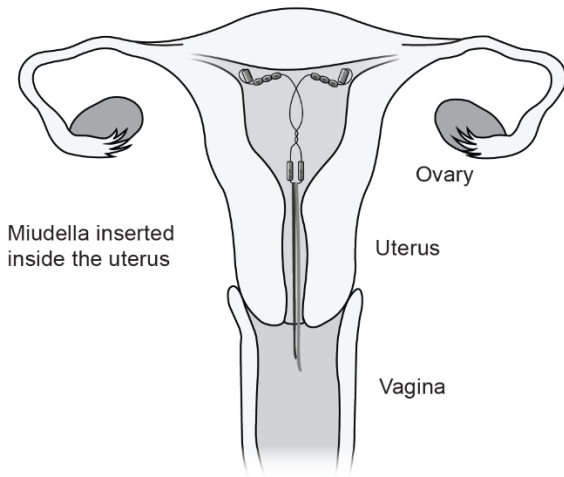
Miudella must be removed at or before 3 years from the date of placement. Your health care provider can place a new Miudella during the same office visit if you choose to continue using Miudella.

**What if I want to stop using Miudella?**

You can stop using Miudella at any time by asking your health care provider to remove it. Your ability to get pregnant goes back to whatever is normal for you as soon as Miudella is removed; therefore, you should immediately use another birth control method if you do not want to become pregnant. Talk to your health care provider about the best birth control method for you because your new method may need to be started 7 days before Miudella is removed in order to prevent pregnancy.

**How does Miudella work?**

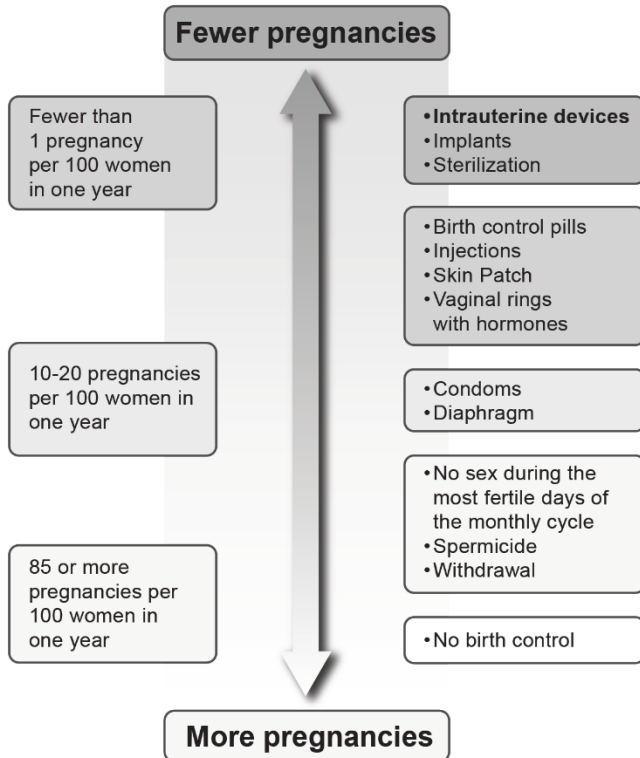
The copper in Miudella works in the uterus by preventing sperm from reaching the egg, or preventing sperm from fertilizing the egg. Miudella does not stop your ovaries from making an egg (ovulating) each month.



### How well does Miudella work as a birth control method?

The following chart shows the chance of getting pregnant while using different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

Miudella, an intrauterine system (IUS), is in the box at the top of the chart.



### Who might use Miudella?

You might choose Miudella if you:

- want hormone-free, long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that can work continuously for up to 3 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is placed in your uterus

**Do not use Miudella if you:**

- are or might be pregnant; Miudella cannot be used as emergency contraception
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- currently have a serious pelvic infection called pelvic inflammatory disease (PID)
- have had a serious pelvic infection after pregnancy or an abortion in the past 3 months
- have or suspect you might have cancer of the uterus or cervix
- have unexplained bleeding from your vagina
- have an untreated lower genital infection now in your cervix
- have Wilson's disease (a disorder in how the body handles copper)
- have an intrauterine system in your uterus already
- are allergic to polypropylene, nickel, titanium or copper

**Before having Miudella placed, tell your health care provider if you have:**

- any of the conditions listed above
- slow heartbeat
- dizziness or history of fainting
- seizures
- recently had a baby or if you are breastfeeding
- have HIV or any other sexually transmitted infection

**How is Miudella placed?**

Miudella is placed in your uterus during an in-office visit.

First, your health care provider will examine your pelvis to find the exact position of your uterus. Your health care provider will then clean your vagina and cervix with an antiseptic solution and then, measure your uterus. Your health care provider will then slide a slim, tapered plastic tube containing Miudella into your uterus. The tube is removed, leaving Miudella inside your uterus. Two soft thread ends will extend into your vagina. The thread ends are just long enough for you to feel with your fingers when doing a self-check. You may experience pain, bleeding, or dizziness during and after placement. Your health care provider may ask you to lie down until you are feeling better, and to get up slowly. Contact your health care provider if you have prolonged symptoms.

**Should I check that Miudella is in place?**

Yes, you should check that Miudella is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your health care provider should teach you how to check that Miudella is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the 2 thread ends. Do not pull on the thread ends.

If you feel changes in the length of the thread ends, or you cannot feel them, or you can feel any other part of Miudella other than the thread ends, Miudella may not be in the right position and may not prevent pregnancy. Use back-up birth control (such as condoms and spermicide) and ask your health care provider to check that Miudella is still in the right place.

**How soon after placement of Miudella should I return to my health care provider?**

Call your health care provider if you have any questions or concerns (see "After Miudella has been placed, when should I call my health care provider?"). Otherwise, you should return to your health care provider for a follow-up visit after your first menses after Miudella is placed to make sure that Miudella is in the right position.

**Can I use tampons with Miudella?**

Yes, tampons may be used with Miudella.

**Can I use a menstrual cup or menstrual disc with Miudella?**

Menstrual cups and menstrual discs are not recommended for use with Miudella. Menstrual cup and menstrual disc use may cause Miudella to become displaced or come out.

**What if I become pregnant while using Miudella?**

Call your health care provider right away if you think you may be pregnant. If you get pregnant while using Miudella, you may have an ectopic pregnancy. This means the pregnancy is not in your uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of an ectopic pregnancy.

Ectopic pregnancy is a medical emergency that requires prompt treatment with surgery or medication. Ectopic pregnancy can cause internal bleeding, infertility and even death.

There are also risks if you get pregnant while using Miudella and the pregnancy is in the uterus. Infection, miscarriage, and premature delivery can occur with pregnancies that continue with an intrauterine system. Because of this, your health care provider may try to remove Miudella, even though removing it may cause a miscarriage. If Miudella cannot be removed, talk with your health care provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your health care provider regularly. Call your health care provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if Miudella can cause long-term effects on the fetus if it stays in place during a pregnancy.

#### **How will Miudella change my periods?**

Your period may become heavier and longer. Sometimes the bleeding is heavier than usual at first then often tapers off over the first few months of use. You may also have spotting between periods.

#### **Is it safe to breastfeed while using Miudella?**

You may use Miudella when you are breastfeeding. Miudella is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. The risk of Miudella becoming attached to (embedded) or going through the wall of the uterus is increased if Miudella is placed while you are breastfeeding.

#### **Will Miudella interfere with sexual intercourse?**

You and your partner should not feel Miudella during intercourse. Miudella is placed in the uterus, not in the vagina. Sometimes your partner may feel the thread ends. If this occurs, or if you or your partner experience pain during sex, talk with your health care provider.

#### **Can I have an MRI with Miudella in place?**

Miudella can be safely scanned with magnetic resonance imaging (MRI) under specific conditions. Before you have an MRI, tell your health care provider that you have Miudella, an intrauterine system (IUS), in place.

#### **Can I have a medical procedure using heat therapy with Miudella in place?**

Before you have a medical procedure using heat therapy tell your health care provider that you have Miudella in place.

#### **What are the possible side effects of Miudella?**

**Miudella can cause serious side effects, including:**

- **ectopic pregnancy and intrauterine pregnancy risks:** There are risks if you become pregnant while using Miudella (see “What if I become pregnant while using Miudella?”).
- **life-threatening infection:** Life-threatening infection can occur within the first few days after an IUS is placed. Call your health care provider immediately if you develop severe pain or fever shortly after Miudella is placed.
- **pelvic inflammatory disease (PID):** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID). PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy, and pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death.  
Tell your health care provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal stomach area pain, painful sex, chills or fever.
- **perforation:** Miudella may become attached to (embedded) or go through the wall of the uterus. This is called perforation. Perforation occurs in about 1 out of 1000 insertions. If this occurs, Miudella may no longer prevent pregnancy. If perforation occurs, Miudella may move outside the uterus and can cause internal scarring, infection, or damage to other organs, pain or infertility and you may need surgery to have Miudella removed. Excessive pain or vaginal bleeding during placement of Miudella, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. You are not protected from pregnancy if Miudella moves outside the wall of the uterus. The risk of perforation is increased if Miudella is inserted while you are breastfeeding.
- **expulsion:** Miudella may partially or completely come out by itself. This is called expulsion. Expulsion occurs in about 3 out of 100 women. Excessive pain or vaginal bleeding during placement of Miudella, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with expulsion. You may become pregnant if Miudella comes out. If you think that Miudella has come out, use a backup birth control method like condoms and spermicide and call your health care provider.
- **reactions after placement or removal:** Some women have had reactions, such as dizziness (syncope), slowed heart rate (bradycardia), or seizures, immediately after Miudella was placed or removed. These reactions were more common among women who have had these conditions before.

#### **Common side effects of Miudella include:**

- **pain or bleeding during and after placement.** You may experience pain, bleeding or dizziness during and after placement. Contact your health care provider if you have prolonged symptoms. Your health care provider will examine you to see if Miudella needs to be removed or replaced.
- **changes in bleeding.** You may have heavier and longer periods with spotting in between. Sometimes the bleeding is heavier than usual at first then often tapers off over the first few months of use. Call your health care provider if the bleeding remains heavier or longer and spotting continues.

Other common side effects include:

- anemia (low red blood cell count)
- pain during sex
- prolonged periods
- vaginal irritation
- backache
- expulsion (complete or partial)
- spotting
- painful periods
- vaginal discharge
- pain and cramping

This is not a complete list of possible side effects with Miudella. For more information, ask your health care provider. Tell your health care provider about any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

You may also report side effects to the manufacturer through the Organon Service Center at 1-844-674-3200.

**After Miudella has been placed, when should I call my health care provider?**

Call your health care provider if you have any questions or concerns about Miudella.

Be sure to call if you:

- think you are pregnant
- have pelvic or abdominal pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections
- are concerned that Miudella may have fallen out (expelled)
- cannot feel Miudella's thread ends
- become HIV positive or your partner becomes HIV positive
- have severe vaginal bleeding that concerns you
- miss a menstrual period
- develop an allergic reaction including itching, swelling, or a rash

**General information about the safe and effective use of Miudella.** Medicines are sometimes prescribed for conditions that are not mentioned in a Patient Information leaflet. You can ask your health care provider for information about Miudella that is written for health care providers.

**For more information, go to [www.miudella.com](http://www.miudella.com) or call the Organon Service Center at 1-844-674-3200.**

Miudella® is a registered trademark of Sebelo Women's Health Inc. The other brands listed are trademarks of their respective owners.



Manufactured for:

Sebelo Women's Health Inc.

Roswell, GA 30076

For more information, call the Organon Service Center at 1-844-674-3200.

This Patient Information has been approved by the U.S. Food and Drug Administration

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