



What is Avibela™?

AVIBELA is a hormone-releasing intrauterine system (also known as a "hormonal IUD") placed in the uterus by a healthcare provider to prevent pregnancy for up to 8 years*. AVIBELA can also be used to treat heavy periods for up to 5 years. Your healthcare provider can remove AVIBELA at any time. Women who want to become pregnant after AVIBELA removal are able to get pregnant within the first year at the same rate as the general population. You could become pregnant as soon as AVIBELA is removed.

How does AVIBELA work?

AVIBELA may work for birth control in several ways including thickening of cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. For heavy menstrual bleeding, the hormone in AVIBELA, levonorgestrel, acts by controlling the monthly development of the womb (uterus) lining, making it thinner, so that there is less bleeding every month. Because AVIBELA releases levonorgestrel into your uterus, only small amounts of the hormone enter your blood. AVIBELA does not provide protection against sexually transmitted diseases.

Is AVIBELA safe?

The safety and efficacy of AVIBELA is supported by multiple Phase 3 clinical trials, for prevention of pregnancy and treatment of heavy menstrual bleeding. The IUD in AVIBELA has been approved by the U.S. FDA and is approved by more than 25 other stringent regulatory authorities. Like all medicines, AVIBELA can cause side effects, although not everybody gets them. See the rest of this material for important information about who can use AVIBELA and possible side effects.

Avibela™
(levonorgestrel-releasing intrauterine system) 52 mg

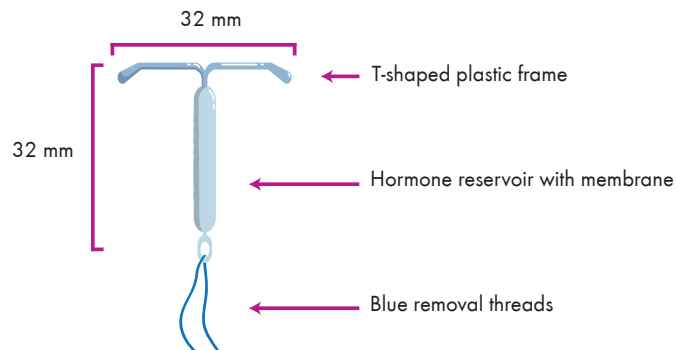


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*Please refer to the approved product labeling in your country to confirm the approved duration of use.

What is the composition of AVIBELA?

AVIBELA is a small, flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel that is often used in birth control pills. Two thin threads are attached to the stem (lower end) of AVIBELA. The threads are the only part of AVIBELA you can feel when AVIBELA is in the uterus; however, unlike a tampon string, the threads do not extend outside the body.



Is AVIBELA effective?

There is fewer than one pregnancy per 100 women who use the hormonal IUD (in one year). AVIBELA is about 99% effective at preventing pregnancy for up to 8 years. A majority of (or 8 out of 10) people with heavy menstrual bleeding experience a reduction of menstrual blood loss by more than half within six months of treatment with AVIBELA. AVIBELA is approved to treat heavy menstrual bleeding for up to 5 years.

Who can and cannot use AVIBELA?

AVIBELA can be used by women of reproductive age, regardless of marital status or whether they have given birth, providing an effective long-term solution for preventing or spacing pregnancies. You may use AVIBELA when you are breastfeeding. See the next page for a list of conditions under which people cannot use AVIBELA.

How is AVIBELA administered?

AVIBELA should only be inserted by a trained healthcare provider during an in-office visit. AVIBELA can be inserted any time the provider can be reasonably certain you are not pregnant. If AVIBELA is inserted after the first 7 days of the menstrual cycle, you should use a barrier method of contraception or abstain from vaginal intercourse for 7 days after insertion to prevent pregnancy. In some cases, AVIBELA can be inserted on the same day you visit a clinic to discuss contraceptive options. You can stop using AVIBELA at any time by asking your healthcare provider to remove it.



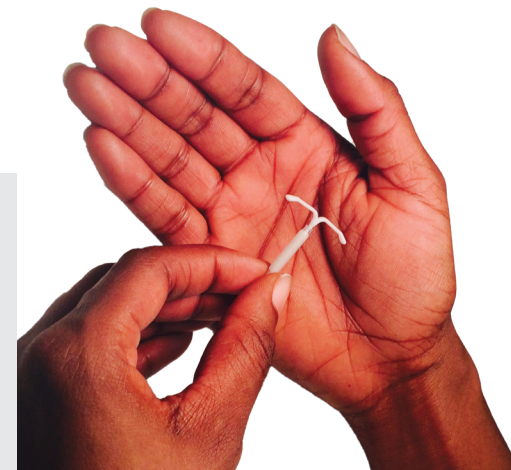
What are the side effects of AVIBELA?

The most common side effects of AVIBELA include vaginal bacterial infection, acne, nausea or vomiting, and abdominal pain, pelvic pain, weight increase, mood changes, back pain, yeast infection of your vulva and vagina, headache, pain during sex, breast pain, depression, vaginal discharge, anxiety, and menstrual-like cramping.

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding and cramping. Some people have heavy bleeding during this time. After you have used AVIBELA for a while, the number of bleeding and spotting days is likely to lessen. For some women, menstrual periods will stop altogether. When AVIBELA is removed, your menstrual periods will likely return to their former pattern.

Source

AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg [Patient Information Leaflet]; Impact RH360; 2023.



AVIBELA

Important Risk Information

Indications

AVIBELA is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 8 years. AVIBELA can also be used to treat heavy periods for up to 5 years.

Do not use AVIBELA if you:

- are or might be pregnant; AVIBELA cannot be used as an emergency contraceptive
- have a serious pelvic infection called pelvic inflammatory disease (PID); PID occurs in less than 1% of users
- have an untreated lower genital infection now
- have had a serious pelvic infection after an abortion or pregnancy within the last 3 months
- can get infections easily. For example, if you:
 - have problems with your immune system
 - have multiple sexual partners or your partner has multiple sexual partners
 - have a history of PID
- have or suspect you might have cancer of the uterus or cervix
- have bleeding from the vagina that has not been explained
- have short-term (acute) liver disease or liver tumor
- have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
- have an intrauterine system in your uterus already
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- are allergic to levonorgestrel, silicone, polyethylene, or barium sulfate

Call your healthcare provider right away if you think you are pregnant. If you get pregnant while using AVIBELA, you may have an ectopic pregnancy, which means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain, especially with missed periods, may be a sign of ectopic pregnancy. Ectopic pregnancy can cause internal bleeding. There are also risks if you get pregnant while using AVIBELA and the pregnancy is in the uterus. Severe infection and premature labor or delivery can occur with pregnancies that continue with an IUS.

Although uncommon, pregnancy while using AVIBELA can be life-threatening and may result in loss of pregnancy or fertility.

Life-threatening infection can occur within the first few days after AVIBELA is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after AVIBELA is placed.

Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. These may be sexually transmitted. You have a higher chance of getting PID or endometritis if you or your partner has sex with other partners. PID or endometritis can cause serious problems, such as infertility, ectopic pregnancy, or pelvic pain that does not go away. More serious cases of PID or endometritis may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID or endometritis can even cause death. Tell your healthcare provider right away if you have any of these signs of PID or endometritis: long-lasting or heavy bleeding, unusual or foul-smelling vaginal discharge, low abdominal or pelvic pain, painful sex, genital lesions or sores, chills, or fever.

AVIBELA may partially go into (become embedded) or go completely through (perforate) the wall of the uterus. If perforation occurs, AVIBELA may move outside the uterus and can cause internal scarring, infection, or damage to other organs. You may need surgery to have AVIBELA removed if it is embedded or perforation occurs. Risk of perforation is increased in breastfeeding people.

AVIBELA may come out of your uterus (expulsion). Expulsion occurs in about 4 out of 100 people, most often in the first year of use. You may become pregnant if AVIBELA comes out. If you think that AVIBELA has come out, use another birth control method (like condoms) or do not have sex (vaginal intercourse) until you are seen by a healthcare provider.

Ovarian cysts may occur but usually disappear.

Bleeding and spotting may increase in the first 3 to 6 months and remain irregular. Periods over time usually become shorter, lighter, or may stop.

AVIBELA does not protect against HIV or STDs.

If any of the side effects get serious, or if you notice any side effects not listed, please tell your healthcare provider.

For more information about AVIBELA, including the Patient Information Leaflet, visit www.avibela.com.