

DO YOU HAVE HEAVY PERIODS?

1 in 3 women have heavy periods¹



Avibela™ 
(levonorgestrel-releasing intrauterine system) 52 mg

Introduction

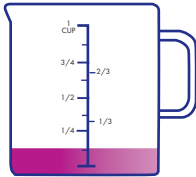
Heavy periods are also known as heavy menstrual bleeding (HMB). Menstrual bleeding can vary among women.



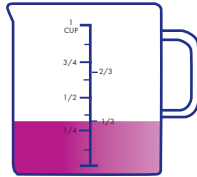
The average volume of blood loss during each menstrual cycle is about 30 mL to 47 mL (2-3 tablespoons) in healthy women who report their menstruation as normal



Women with heavy periods experience blood loss of 80 mL or more, or about 1/3 cup, during menstrual cycles



Typical period,
30 mL to 47 mL



Heavy period,
≥80 mL



Avibela™ is a contraceptive method that also helps control heavy periods

You may have heavy periods if you:



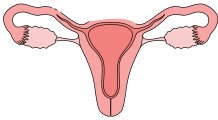
- Soak through one or more sanitary pads or tampons every hour for several consecutive hours
- Need to use double sanitary protection to control your menstrual flow
- Wake up to change sanitary protection during the night
- Have menstrual periods lasting longer than a week
- Pass blood clots larger than 1 inch (~25 mm)

INDICATIONS

AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg is a hormone-releasing system placed in your uterus to prevent pregnancy for up to 8 years. AVIBELA also treats heavy periods for up to 5 years in women who choose to use contraception placed in the uterus.

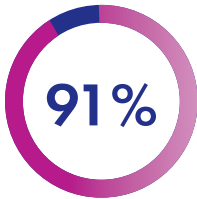
AVIBELA:

- Is a proven, long-term, reversible method of contraception
- Is about 99% effective at preventing pregnancy for up to 8 years
- Helps treat heavy periods, also known as heavy menstrual bleeding (HMB), for up to 5 years in women who choose an IUD for contraception
- Can be used whether or not you have been pregnant or have had a baby

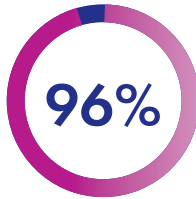


IN A CLINICAL STUDY, AVIBELA WAS SHOWN TO SUCCESSFULLY TREAT THE MAJORITY OF (8 OUT OF 10) WOMEN WITH HEAVY PERIODS*

AVIBELA rapidly reduced menstrual blood loss by



AT MONTH 3
(mid-study)



AT MONTH 6
(end-of-study)



The number of bleeding and spotting days may increase in the first 3 to 6 months of use. Then, the number of bleeding and spotting days usually decreases but bleeding may remain irregular.

AVIBELA can be used for the treatment of heavy periods for up to 5 years in women who choose an IUD for contraception

If you need continued treatment for heavy periods after 5 years, your healthcare provider can remove AVIBELA and place a new AVIBELA during the same office visit.



This means these women's menstrual blood loss was reduced to less than 80 mL and reduced by more than half by the end of treatment at 6 months.

WHEN CAN AVIBELA BE INSERTED?

AVIBELA can be inserted during an in-office visit



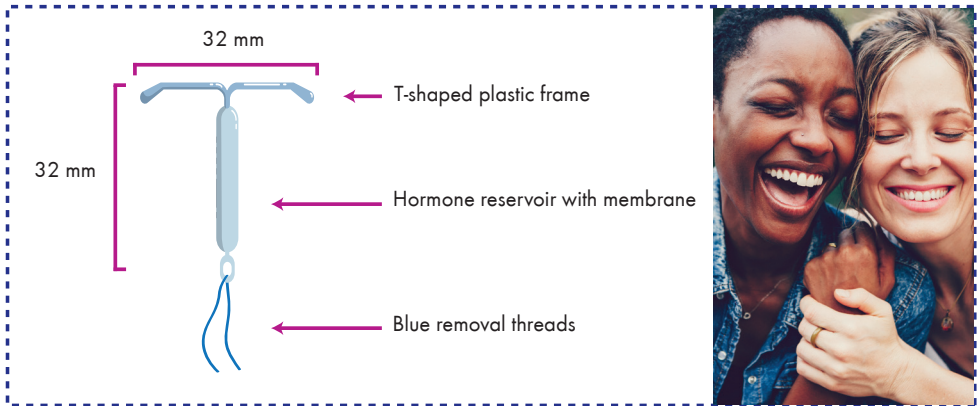
Insertion is performed by your healthcare provider



AVIBELA can be inserted if you are currently using another form of contraception, like the pill, or if you are not using anything for contraception

You may experience pain, bleeding, or dizziness during and after insertion. If your symptoms do not pass within 30 minutes after insertion, AVIBELA may not have been placed correctly. Your healthcare provider will examine you to see if AVIBELA needs to be removed or replaced.

A BACKUP CONTRACEPTIVE METHOD, SUCH AS CONDOMS, MAY NEED TO BE USED FOR 7 DAYS AFTER AVIBELA INSERTION TO PREVENT PREGNANCY.



AFTER AVIBELA IS PLACED

Your healthcare provider will explain:



How you can check the threads, once a month, to make sure AVIBELA is still in place



You may need a follow-up appointment 4 to 6 weeks after placement and routine visits thereafter to make sure that AVIBELA is in the right position



When AVIBELA is in your uterus, the threads are the only part of AVIBELA you should feel; however, unlike a tampon string, the threads do not extend outside your body

WILL MY PARTNER FEEL THE IUD DURING SEX?

You and your partner should not feel AVIBELA during intercourse because the IUD is placed in the uterus, not the vagina. However, there is a chance that your partner may feel the threads. If this occurs, or if you or your partner experiences pain during sex, talk with your healthcare provider.

WILL AVIBELA AFFECT MY PERIOD?

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 women have heavy bleeding during this time.

After you have used AVIBELA for a while, the number of days you experience bleeding and spotting 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.

If you have any concerns that you may be pregnant while using AVIBELA, contact your healthcare provider and, if possible, complete a urine pregnancy test.

TALK TO YOUR HEALTHCARE PROVIDER

If you're considering AVIBELA, you and your healthcare provider should discuss your general health and any medical conditions you have or have had. Some topics to also mention include:

- Any known abnormalities in the shape of your uterus
- If you've had a baby recently or are breastfeeding
- Any medication you're taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- If you have any sexually transmitted diseases (STDs) or sexually transmitted infections (STIs)



**Learn more about AVIBELA and ask your healthcare provider
if AVIBELA might be right for you**

Source: AVIBELA Patient Information Leaflet

1 Hallberg L, Högdahl AM, Nilsson L, Rybo G. Menstrual blood loss—a population study. Variation at different ages and attempts to define normality. *Acta Obstet Gynecol Scand.* 1966;45(3):320-51. doi: 10.3109/00016346609158455.

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.