

Patient Information Leaflet

AVIBELA® 20 micrograms/24 hours Intrauterine Delivery System Levonorgestrel

Scheduling Status: NS1, S2, PIM, POM, PP

AVIBELA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare provider. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in reproductive health.
- You should also learn about other birth control methods to choose the one that is best for you.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

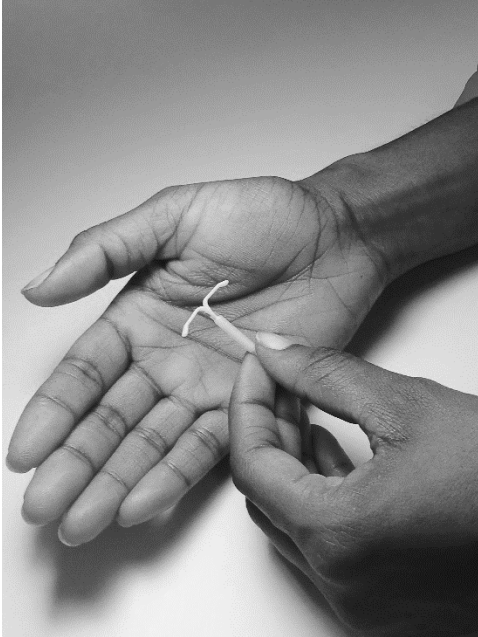
1. What AVIBELA is and what it is used for
2. What you need to know before you use AVIBELA
3. How to use AVIBELA
4. Possible side effects
5. How to store AVIBELA
6. Contents of the pack and other information

1. What AVIBELA is and what it is used for

- 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 menstrual bleeding (heavy periods), for up to 5 years.
- AVIBELA contains 52 mg of levonorgestrel, which is released slowly over time.
- AVIBELA can be removed by your healthcare provider at any time.
- AVIBELA can be used whether or not you have given birth to a child.

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. Because AVIBELA releases levonorgestrel into your uterus, only small amounts of the hormone enter your blood. AVIBELA does not contain estrogen.

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 your uterus; however, unlike a tampon string, the threads do not extend outside your body.



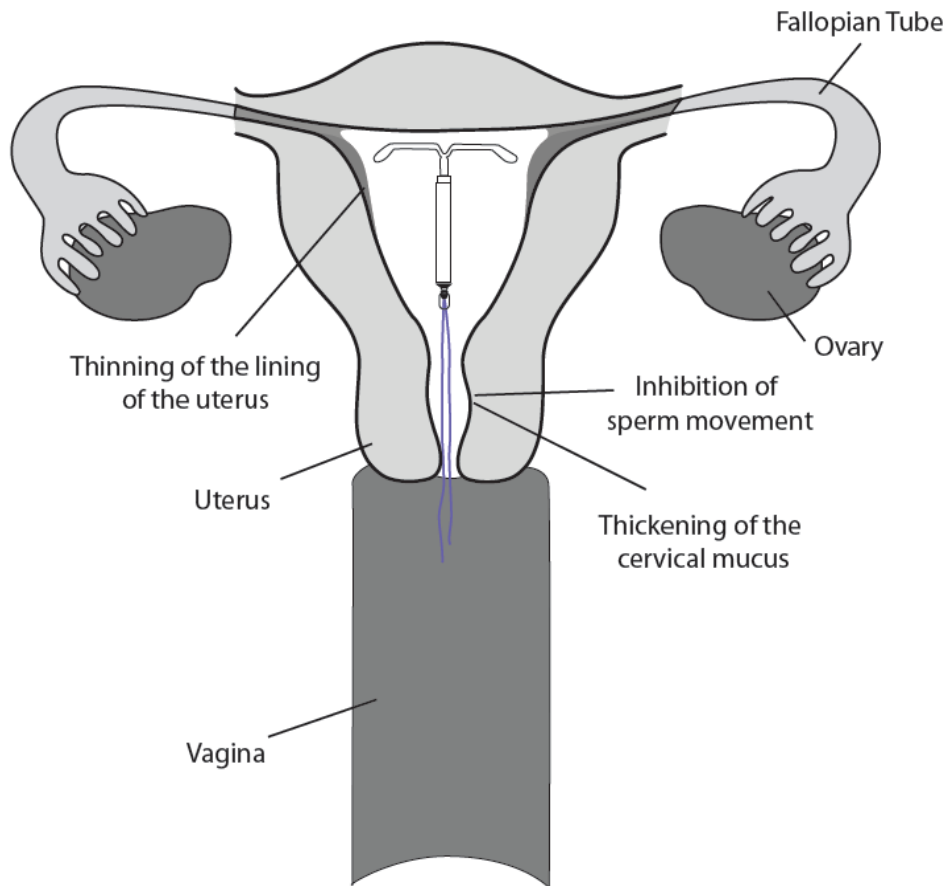
AVIBELA is small



and flexible

How does AVIBELA work for birth control?

AVIBELA may work for birth control in several ways including thickening of cervical mucus, inhibiting sperm movement, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.



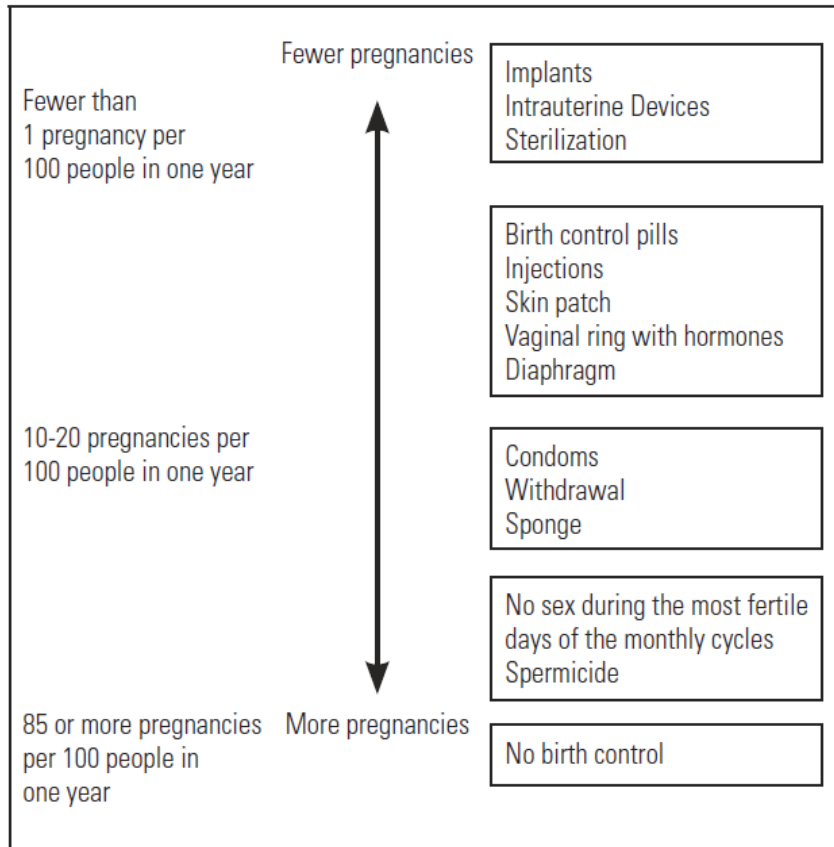
How does AVIBELA work for treating heavy menstrual bleeding?

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.

How well does AVIBELA work for birth control?

The following chart shows the chance of getting pregnant for people who use 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 at the bottom of the chart shows the chance of getting pregnant for people who do not use birth control and are trying to get pregnant.

AVIBELA, an intrauterine system (IUS), is also known as an intrauterine device (IUD), which is listed in the box at the top of the chart.



How well does AVIBELA work for treating heavy menstrual bleeding?

In the clinical trial performed in participants with heavy menstrual bleeding and treated with AVIBELA, the majority of (or 8 out of 10) participants were treated successfully. That is, their menstrual cycle blood loss was reduced to less than 80 mL and reduced by more than half by the end of treatment at six months.

2. What you need to know before you use AVIBELA

You might choose AVIBELA if you:

- want birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to 8 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 the uterus
- want birth control that does not contain estrogen
- want to treat heavy menstrual bleeding

Not all people can use AVIBELA.

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)

- 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

Before having AVIBELA placed, tell your healthcare provider if you have or have had any medical conditions, including those listed above and below:

- a heart attack
- a stroke
- been born with heart disease or have problems with your heart valves
- problems with blood clotting or take medicine to reduce clotting
- high blood pressure
- recently had a baby or if you are breastfeeding
- severe migraine headaches
- severe or frequent headaches
- AIDS, HIV, or any other sexually transmitted infection

AVIBELA must be removed after 8 years. Your healthcare provider can place a new AVIBELA during the same office visit if you choose to continue using AVIBELA.

For continued treatment of heavy menstrual flow after 5 years, your healthcare professional can remove AVIBELA and place a new AVIBELA during the same office visit.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What if I become pregnant while using AVIBELA?

Call your healthcare provider right away if you think you are pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using AVIBELA, you may have an ectopic pregnancy. This 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 is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

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

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare 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 AVIBELA can cause long-term effects on the fetus if it stays in place during a pregnancy.

What if I change my mind about birth control and want to become pregnant in less than 8 years?

Your healthcare provider can remove AVIBELA at any time. You could become pregnant as soon as AVIBELA is removed. About 5 out of 6 people who want to become pregnant will become pregnant sometime in the first year after AVIBELA is removed.

Is it safe to breastfeed while using AVIBELA?

You may use AVIBELA when you are breastfeeding. AVIBELA is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among people using progestin-only birth control pills. The risk of AVIBELA becoming attached to (embedded) or going through the wall of the uterus is increased when AVIBELA is inserted while you are breastfeeding.

Driving and using machines

There are no known effects on the ability to drive or use machines.

3. How to use AVIBELA

AVIBELA is placed by your healthcare provider during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a plastic tube containing AVIBELA through the cervix into your uterus. Your healthcare provider will then remove the plastic tube and leave AVIBELA in your uterus. Your healthcare provider will trim the threads to the right length.

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

How soon after placement of AVIBELA should I return to my healthcare provider?

Call your healthcare provider if you have any questions or concerns (see “When should I call my healthcare provider?”). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after AVIBELA is placed to make sure that AVIBELA is in the right position, and routine visits thereafter. Follow-up plans may vary according to your needs.

After AVIBELA has been placed, when should I call my healthcare provider?

Call your healthcare provider if you have any concerns about AVIBELA. Be sure to call if you:

- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms, or chills
- might have been exposed to a sexually transmitted infection (STI)
- are concerned that AVIBELA may have been expelled (came out)
- cannot feel AVIBELA's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes (these may be signs of liver problems)
- have had a stroke or heart attack
- or your partner become(s) HIV positive
- have severe vaginal bleeding, bleeding that lasts a long time, or you miss your period

Should I check that AVIBELA is in place?

Yes, you should check that AVIBELA is in proper position by feeling the threads. It is a good habit to do this every month. Your healthcare provider should teach you how to check that AVIBELA 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 threads. Do not pull on the threads.

If you feel more than just the threads or if you cannot feel the threads, AVIBELA may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms) and ask your healthcare provider to check that AVIBELA is still in the right place.

How will AVIBELA change my periods?

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 people, menstrual periods will stop altogether. When AVIBELA is removed, your menstrual periods will likely return to their former pattern.

Can I use tampons or a menstrual cup with AVIBELA?

Yes, tampons or menstrual cups may be used with AVIBELA. Change tampons or menstrual cups with care to avoid pulling the threads of AVIBELA. If you think you may have pulled AVIBELA out of place, avoid intercourse or use a non-hormonal back-up birth control (such as condoms), and contact your healthcare professional.

Will AVIBELA interfere with sexual intercourse?

You and your partner should not feel AVIBELA during intercourse. AVIBELA is placed in the uterus, not in the vagina. In some cases, your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Can I have a magnetic resonance imaging (MRI) procedure with AVIBELA in place?

Yes, AVIBELA should not interfere with imaging. Tell your healthcare professional you have an intrauterine contraceptive in place.

What if I want to stop using AVIBELA?

AVIBELA is intended for use up to 8 years, but you can stop using AVIBELA at any time by asking your healthcare provider to remove it. You could become pregnant as soon as AVIBELA is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare provider about the best birth control methods for you, because your method may need to be started 7 days before AVIBELA is removed to prevent pregnancy.

4. Possible side effects of AVIBELA

Like all medicines, AVIBELA can cause side effects, although not everybody gets them.

AVIBELA can cause serious side effects, including:

- **ectopic pregnancy.** If you get pregnant while using AVIBELA, you might have an ectopic pregnancy. This 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 is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.
- **intrauterine pregnancy risks.** There are also risks if you get pregnant while using AVIBELA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labor, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove AVIBELA, even though removing it may cause a miscarriage. If AVIBELA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy. If, after seeing your healthcare provider, you choose to continue your pregnancy, see your healthcare provider regularly. Call your healthcare 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 AVIBELA can cause long-term effects on the fetus if it stays in place during a pregnancy.
- **life-threatening infection.** 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.

- **pelvic inflammatory disease (PID) or endometritis.** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID and endometritis are usually 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. PID is usually treated with antibiotics. 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.
- **perforation.** AVIBELA may partially go into the wall of the uterus (become embedded) or go completely through the wall of the uterus (perforate). If this occurs, AVIBELA may no longer prevent pregnancy. 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. The risk of perforation is increased in breastfeeding people.
- **expulsion.** 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.
- **Cysts on the ovary.** Some people using AVIBELA develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 to 3 months. However, a cyst can cause pain and sometimes cysts will need surgery.
- **changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.

The most common side effects of AVIBELA include:

- | | |
|---------------------------|---|
| • acne | • vaginal bacterial infection |
| • headache | • yeast infection of your vulva and vagina (vulvovaginal) |
| • breast pain | • nausea or vomiting |
| • abdominal pain | • weight increase |
| • pelvic pain | • mood changes |
| • menstrual-like cramping | • anxiety |
| • pain during sex | • depression |
| • back pain | |
| • vaginal discharge | |
- **pain, bleeding, or dizziness during and after insertion.** If these symptoms do not stop within 30 minutes after insertion, AVIBELA may not have been placed correctly, or these

may be symptoms of perforation or expulsion. Your healthcare provider should examine you to see if AVIBELA needs to be removed or replaced.

- **missed menstrual periods.** About 2 out of 10 people stop having periods after 1 year of AVIBELA use. If you have any concerns that you may be pregnant while using AVIBELA, do a urine pregnancy test and call your healthcare provider. When AVIBELA is removed, your menstrual periods will usually return to their previous pattern.

These are not all the possible side effects of using AVIBELA. For more information, ask your healthcare provider.

Reporting of side effects

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

5. How to store AVIBELA

Store in the original package. Keep the pouch in the outer carton in order to protect from light. Do not open the AVIBELA pack. Only your healthcare provider should do this.

Keep this medicine out of the sight and reach of children.

Do not use the system after the expiry date which is stated on the label and the outer pack after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What AVIBELA contains

AVIBELA contains 52 mg of levonorgestrel, the active substance. The hormone is contained within a substance called polydimethylsiloxane. This is surrounded by a membrane (skin) also made of polydimethylsiloxane.

What AVIBELA looks like and contents of the pack

AVIBELA consists of a small T-shaped frame made from a plastic called polyethylene. This structure provides a device for releasing the hormone gradually into the uterus (womb). There are two fine threads, made of polypropylene and copper phthalocyanine blue, attached to the bottom of the T-frame. These allow easy removal and allow you or your healthcare provider to check that AVIBELA is in place.

Each pack contains one AVIBELA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet.

You can ask your healthcare provider for information about AVIBELA that is written for health professionals.

Supplier and Manufacturer

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