

## Patient Information Leaflet

### AVIBELA

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

Please read this leaflet carefully before you decide if AVIBELA is right for you. If you need some more information, consult your doctor or pharmacist. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. You should also learn about other birth control methods to choose the one that is best for you. For prescription only medicinal products, additionally do not give this medicinal product to other persons, even if their symptoms seem similar to yours.

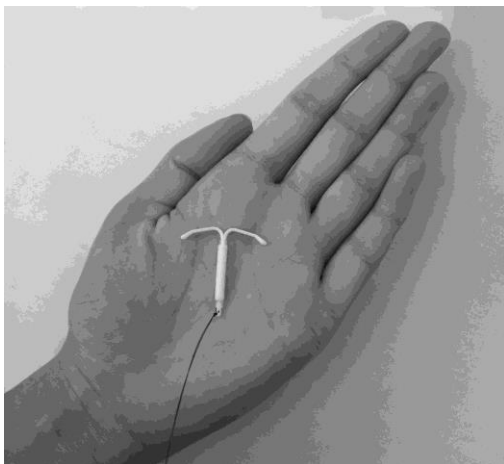
#### What is AVIBELA?

- AVIBELA is a hormone-releasing system inserted in your uterus by your healthcare provider to prevent pregnancy for up to 5 years.
- AVIBELA contains 52 mg levonorgestrel, which is released slowly over 5 years.
- AVIBELA can also be used to treat heavy menstrual bleeding (heavy periods).
- 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 (LNG) that is often used in birth control pills. Because AVIBELA releases LNG into your uterus, only small amounts of the hormone enter your blood. AVIBELA does not contain estrogen.

One system contains 52 mg of levonorgestrel. Initially, levonorgestrel is released at approximately 20 mcg/day. This rate decreases progressively after placement. Inactive ingredients include polydimethylsiloxane (PDMS), low density polyethylene, barium sulfate, and blue polypropylene (with copper containing colorant).

Two thin threads are attached to the stem (lower end) of AVIBELA. The threads are the only part of AVIBELA you should 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**

### **What if I need birth control for more than 5 years?**

AVIBELA must be removed after 5 years. Your healthcare provider can insert a new AVIBELA during the same office visit if you choose to continue using AVIBELA.

### **What if I want to stop using AVIBELA?**

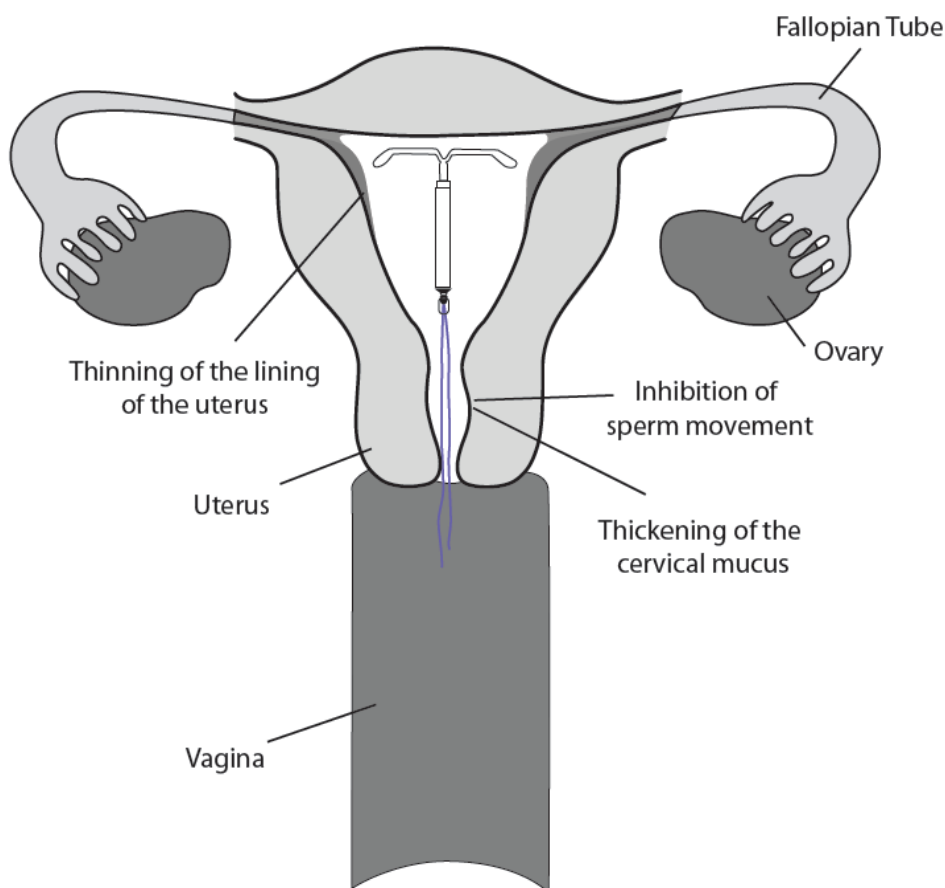
AVIBELA is intended for use up to 5 years, but you can stop using AVIBELA at any time by asking your healthcare provider to remove it. You could become pregnant as soon as AVIBELA is removed, so you should use another method of birth control if you do not want to become pregnant. Discuss your options with your healthcare provider, because certain methods should be started 7 days before AVIBELA is removed to ensure continued birth control.

### **What if I change my mind about birth control and want to become pregnant in less than 5 years?**

Your healthcare provider can remove AVIBELA at any time. You could become pregnant as soon as AVIBELA is removed. About 6 out of 7 women who want to become pregnant will become pregnant sometime in the first year after AVIBELA is removed.

### **How does AVIBELA work for contraception?**

AVIBELA may work for contraception in several ways, including thickening of cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy. The thinning of the lining of the uterus also reduces bleeding and is how AVIBELA works to treat heavy menstrual bleeding.



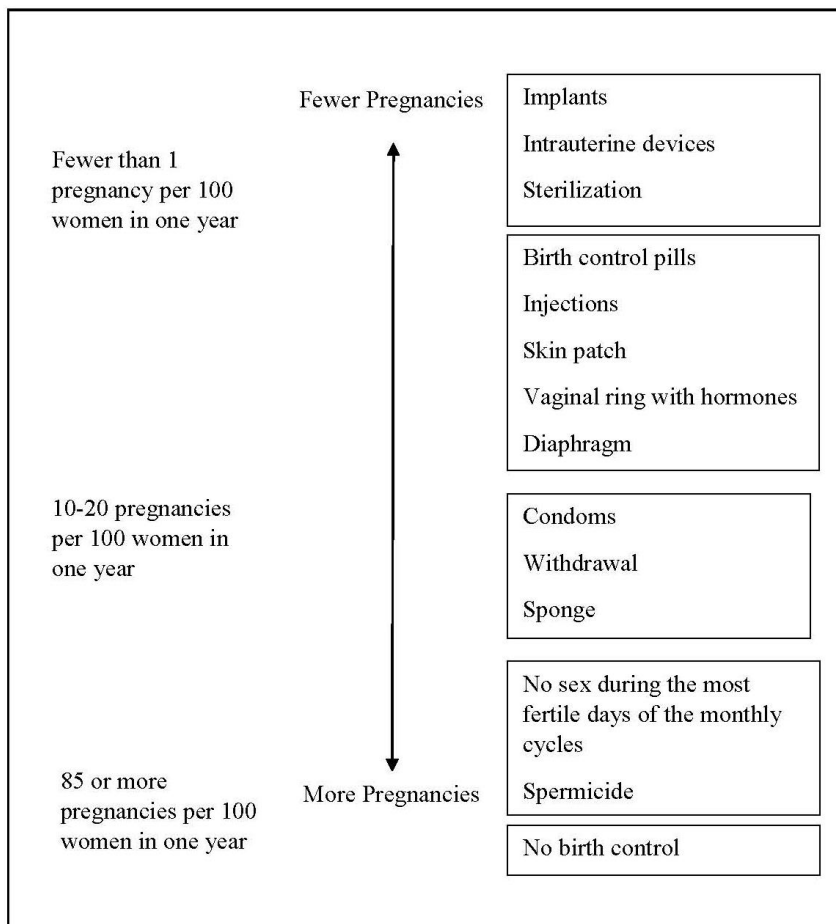
### How does AVIBELA work for heavy menstrual bleeding?

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.

### How well does AVIBELA work for contraception?

The following chart shows the chance of getting pregnant for women 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 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.

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



### How well does AVIBELA work for treating heavy menstrual bleeding?

AVIBELA usually achieves a significant reduction of menstrual blood loss within six months.

### Who might 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 a maximum of 5 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 inserted in the uterus
- want birth control that does not contain estrogen
- want to treat heavy menstrual bleeding

**Who should not 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) or endometritis
- have an untreated lower genital infection now
- 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
  - use or abuse intravenous drugs
- 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 inserted, tell your healthcare provider if you:**

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

- have any other medical conditions

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

### **How is AVIBELA inserted?**

AVIBELA is inserted 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 slim 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. Insertion takes only a few minutes.

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 inserted correctly. Your healthcare provider will examine you to see if AVIBELA needs to be removed or replaced.

### **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 1 time a 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 spermicide) and ask your healthcare provider to check that AVIBELA is still in the right place.

If AVIBELA is accidentally removed and you had vaginal intercourse within the preceding 24 hours, you may be at risk of pregnancy, and should talk to a healthcare provider.

### **How soon after insertion 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 inserted to make sure that AVIBELA is in the right position.

### **Can I use tampons with AVIBELA?**

Tampons may be used with AVIBELA.

### **What if I become pregnant while using AVIBELA?**

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. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain 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 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.

### **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. Some women 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.

If you have any concerns that you may be pregnant while using AVIBELA, do a urine pregnancy test or call your healthcare provider.

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

You may use AVIBELA when you are breastfeeding if more than 6 weeks have passed since you had your baby. If 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 women using progestin-only birth control pills.

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

You and your partner should not feel AVIBELA during intercourse. AVIBELA is inserted 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 an MRI with AVIBELA in place?**

AVIBELA is MR Safe. It is safe to have an MRI following AVIBELA insertion.

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

#### **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 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 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 inserted. Call your healthcare provider immediately if you develop severe pain or fever shortly after AVIBELA is inserted.

- **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 or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID can even cause death.

Tell your healthcare provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal pain, painful sex, chills, or fever.

- **perforation.** AVIBELA may become attached to (embedded) or go through the wall of the uterus. This is called perforation (or embedment). 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 perforation or embedment occurs. The risk of perforation is increased in breastfeeding women.
- **expulsion.** AVIBELA may come out of your uterus. This is called expulsion. Expulsion occurs in about 4 out of 100 women, 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 and spermicide or do not have sex (vaginal intercourse) until you are seen by a healthcare provider.

**The most common side effects of AVIBELA include:**

- vaginal bacterial infection
- yeast infection of the outer part of your vagina (vulvovaginal)
- acne
- headache
- nausea/vomiting
- pain during sex
- abdominal pain
- breast pain
- pelvic pain
- depression
- weight increase
- vaginal discharge
- mood changes
- anxiety
- Pain, bleeding, or dizziness during and after insertion. If these symptoms do not stop within 30 minutes after insertion, AVIBELA may not have been inserted correctly. Your healthcare provider will examine you to see if AVIBELA needs to be removed or replaced.
- Missed menstrual periods. About 1 out of 5 women 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 or call your healthcare provider. When AVIBELA is removed, your menstrual periods will usually return to your previous pattern.

- 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.
- Cysts on the ovary. Some women 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.

This is not a complete list of possible side effects with AVIBELA. For more information, ask your healthcare provider. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

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

### **After AVIBELA has been inserted, 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 be exposed to sexually transmitted infections (STIs)
- are concerned that the IUS 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
- you or your partner becomes HIV positive
- have severe vaginal bleeding or bleeding that concerns you

### **General information about the safe and effective use of AVIBELA.**

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

This leaflet summarizes the most important information about AVIBELA. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about AVIBELA that is written for health professionals.

Manufactured by:

Odyssea Pharma, SPRL, Belgium

An affiliated company of Allergan Pharma, Inc.



The Holder of the Product License:

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