**PATIENT INFORMATION LEAFLET**
**AVIBELA**

**SCHEDULING STATUS:**

S4

**AVIBELA** 20 micrograms/24 hours Intrauterine Delivery System

Levonorgestrel

Sugar free

**AVIBELA does not protect against human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS) and other sexually transmitted disease (STDs).**

**Read all of this leaflet carefully before AVIBELA is inserted**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist. This information does not take the place of talking with your gynaecologist 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.
- 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 AVIBELA is inserted
3. How AVIBELA is used
4. Possible side effects
5. How to store AVIBELA
6. Contents of the pack and other information

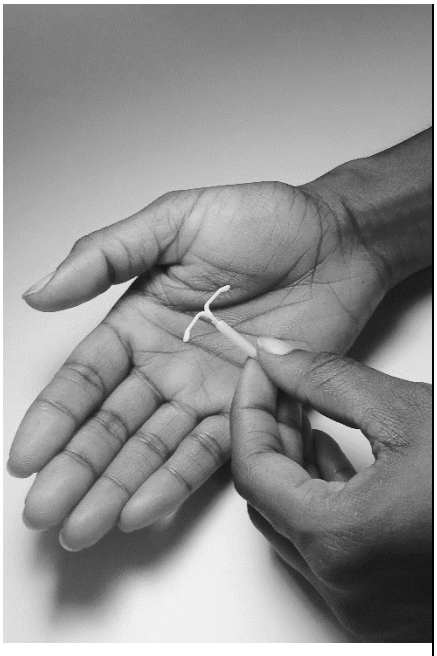
**PATIENT INFORMATION LEAFLET**
**AVIBELA**

## 1. What AVIBELA is and what it is used for

- AVIBELA contains levonorgestrel and is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 6 years
- AVIBELA can also be used to treat heavy menstrual bleeding (heavy periods)
- AVIBELA contains 52 mg of levonorgestrel, which is released slowly over 6 years
- 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.

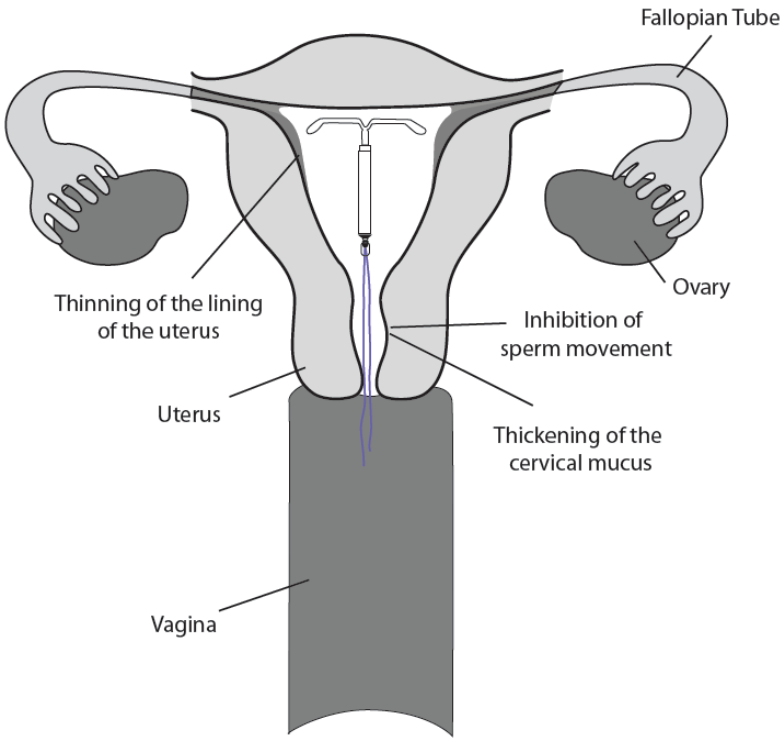




AVIBELA is small and flexible.

**How does AVIBELA work for birth control?**

AVIBELA may work for birth control in several ways including thickening of cervical mucus, inhibiting sperm movement, reducing sperm survival, 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 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.

## 2. What you need to know before you insert AVIBELA

**AVIBELA should not be inserted :**

- if you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of

AVIBELA (see section 6)

- if you are pregnant or suspect you are pregnant
- if you have an infection of your genitals
- if you have an infection of your female reproductive organs called pelvic inflammatory disease (PID) or you have any sexually transmitted disease (STDs) including the clap (bacterial infection also called gonorrhoea)
- if you have a painful disorder of the female reproductive organs called endometriosis, where the tissue which normally lines your uterus, grows outside your uterus, after giving birth
- if you had an abortion in the last three months, which was infected
- if you have inflammation of the cervix (the lower narrow end of the uterus that opens into the vagina) which includes symptoms like bleeding between menstrual periods, pain during sex or any abnormal vaginal discharge
- if you have inflammation of the vagina, which include symptoms like discharge, itching and pain in the vaginal area
- if you have abnormal growth of cells on the surface of your cervix or type of cervical cancer called neoplasm (as diagnosed by your doctor)
- if you have cancer of the uterus (womb)
- if you have a certain type of cancer which are hormone-sensitive, including breast cancer
- if you have abnormal bleeding from your womb, which have not been diagnosed
- if you have any abnormality of the uterus (womb) which can affect the insertion and/or holding of the intra-uterine device (IUD)
- if you have severe liver disease or liver cancer
- if you have another IUD which has not been removed
- if you have an illness that increases your likelihood to get infections
- if you have acute blood cancers, like leukaemia, unless you are in remission

- if you had recent abnormal cell growth in tissue that forms in the uterus (womb) while pregnancy hormone levels remain high.

**Warnings and precautions**

Tell your doctor or healthcare professional before insertion of the IUD if you:

- had a heart attack
- 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 or partial loss of vision associated with migraine headaches
- have severe or frequent headaches
- have AIDS, HIV, or any other sexually transmitted infection.

Special care should be taken with AVIBELA:

- if you develop blood clots with symptoms including pain in one leg and/or swelling, sudden severe pain in the chest which may extend to the left arm, sudden breathlessness, sudden onset of coughing, any unusual, severe, long-lasting headache, sudden partial or complete loss of eye sight, double-vision, slurred speech or struggling to communicate, sensation that the environment is moving or spinning, collapse with or without a fit, weakness or marked numbness suddenly affecting one side of or one part of the body, involuntary or uncontrollable movements or actions of the body, severe pain in abdomen caused by a condition called ‘acute’ abdomen

- if you develop blood clots in your eyes with symptoms like unexplained partial or complete loss of eyesight, bulging eyes or double vision, swelling of your optic nerve which may affect your vision or sudden change in eyesight due to a condition called retinal vascular lesions
- if you have been born with heart disease or have problems with your heart valves
- you may feel like fainting or experience lower than normal heart rate when the IUD is being inserted
- if you suffer from diabetes, your blood glucose levels should be monitored as AVIBELA may affect your glucose tolerance
- if you experience abnormal/changes in your period bleeding pattern, like spotting, irregular bleeding, heavy bleeding, infrequent menstrual periods, or absence of menstrual period. During the first 3 - 6months of AVIBELA use, you may experience more than normal bleeding or spotting days and abnormal bleeding patterns may develop. Thereafter, the number of bleeding and spotting days may be less, but bleeding may still be irregular
- if you experience a heavier menstrual flow or unexplained bleeding, especially if you experience more cramping, it may indicate that AVIBELA has come out and you should be evaluated by your doctor
- if you develop lower abdominal pain or pain in your pelvis, fever, chill, unusual and smelly vaginal discharge, unexplained bleeding, sores on your genitals or experience pain during sex, notify your doctor immediately. You may have developed a condition called pelvic inflammatory disease
- if you had multiple sexual partners or your partner had multiple sex partners, you may be at risk to develop a sexually transmitted disease (STD). AVIBELA does not protect against STDs, and you may have a higher risk to develop the condition called pelvic inflammatory disease or inflammation of the womb. You may also have a higher risk to develop these conditions again, if you previously had any of these. Also, if you have blood cancer, AIDS or using illegal substances via injection, you may also have a higher risk to develop these

conditions. These conditions may also be without any symptoms but can cause damage to your female reproductive organs

- if you develop a bacterial infection called actinomycosis. Symptoms include hard lump in the jaw that is not usually painful, muscle spasms or “locked jaw”, draining sores in the skin, fever, mild or no pain, swelling or a hard, red to reddish-purple lump on the face or upper neck and weight loss
- AVIBELA may be expelled (come out) partially or completely, and may no longer be effective as birth control
- AVIBELA may perforate (pierce) your womb wall or cervix, mostly during insertion. If you experience severe pain and continued bleeding after insertion, please contact your doctor immediately, as delay in removal of AVIBELA may result in moving of the IUD outside your womb, adhesions (bands of scar like tissue), inflammation of the intestines, piercing/perforation of intestines, blockages in intestines, abscesses, and damage to the internal organs of the body
- if you have lower abdominal pain, in connection with missed periods or if your period starts and you did not have any periods while AVIBELA was inserted, you may have developed a pregnancy outside of your womb. You should contact your doctor immediately. This may affect your fertility
- you may develop cysts on your ovaries; however, they usually disappear in 2 - 3 months. Symptoms of ovarian cysts include pain in your pelvis, abdominal pain, and painful sex
- if you have breast cancer you should not use any form of hormonal birth-control, as some of the breast cancers are sensitive to these hormones.
- if you are a woman in menopause
- if you have a pigmentation disorder of the skin, called chloasma, in which large brown patches form on the skin. Avoid exposure to the sun or ultraviolet light.

**Children and adolescents**

AVIBELA should not be used before the first occurrence of menstruation and children below the age of 16 years.

**Other medicines and AVIBELA**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines)

- if you take any medicine which has an effect on the liver enzymes i.e.
    - primidone (used to treat seizures and shakiness)
    - barbiturates e.g. phenobarbitone (used to treat sleep disorders, anxiety, migraine)
    - phenytoin, carbamazepine, felbamate (used to treat epilepsy)
    - rifampicin (used to treat tuberculosis)
    - topiramate (used to treat epilepsy and migraines)
    - griseofulvin (used to treat fungus infections of nails, scalp, and skin)
    - rifabutin (used to prevent bacterial infections in patients with human immunodeficiency virus (HIV) infection
    - nevirapine (used to treat HIV) infection
    - efavirenz (used to treat HIV infection)
    - products containing St. John's wort.

**Pregnancy, breastfeeding and fertility**

AVIBELA should not be inserted if you are or suspect you are pregnant. If you suspect you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before AVIBELA is inserted. 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 labour, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). 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 have 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 foetus if it stays in place during a pregnancy.

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.

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. You may have a higher risk that AVIBELA may attach to (embedded) or go through the walls of the womb (uterus) if you are

breastfeeding. If you want to breastfeed your baby, you should ask a healthcare provider for advice on the risks and benefits while using AVIBELA.

**Driving and using machines**

It is not always possible to predict to what extent AVIBELA may interfere with your daily activities. There are no known effects on the ability to drive or use machines.

**3. How AVIBELA is used**

AVIBELA is inserted by your healthcare provider.

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. Otherwise, you should return to your healthcare provider for a follow-up visit 4 - 6 weeks after AVIBELA is placed to make sure that AVIBELA is in the right position.

**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 disease (STD)
- 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)
- had a stroke or heart attack
- or your partner(s) become(s) HIV positive
- develop blood cancer (leukaemia)
- 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 spermicide) 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 - 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 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.

**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.

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

AVIBELA is intended for use up to 6 years for contraception, 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**

AVIBELA is inserted by your healthcare provider.

Not all side effects reported for AVIBELA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using AVIBELA, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- **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
- **ntrauterine pregnancy risks:** There are also risks if you get pregnant while using AVIBELA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labour, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUD). 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 foetus 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 IUD 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 vaginal discharge, low abdominal pain, painful sex, 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 women
- **expulsion:** AVIBELA may come out of your uterus (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
- **cysts on the ovary:** Some women using AVIBELA develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 - 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.

These are all serious side effects. You may need urgent medical attention.

Very common and common side effects of AVIBELA include:

- vaginal infection caused by bacteria, yeast infection of the outer part of your vagina (vulvovaginal)
- anxiety, depression, mood changes, sleeplessness, lower sex drive
- headache, migraine (a severe headache, often accompanied by nausea and sensitivity to light and sound), near fainting, dizziness, fainting
- nausea, pain/discomfort in your abdomen, bloating and swelling in the belly area, constipation, indigestion, diarrhoea, vomiting
- acne (pimples), hair loss
- back pain, pain in legs or arms
- severe and frequent menstrual cramps and pain during your period, pain during sex, breast pain/tenderness, pain/discomfort in your pelvis, spasm of your womb (uterus), discharge from your vagina, dryness/discomfort of your vagina and genital area, menstrual bleeding that lasts more than 7 days, bleeding after having sex (not related to your period), funny odour from your vagina, any vaginal/womb bleeding unrelated to your normal period, including spotting, infrequent menstrual periods, heavy menstrual bleeding
- weight gain, abnormal ovaries as detected by ultrasound
- bleeding after device has been inserted, device is expelled (ejected), pain during the procedure of inserting the device, device moved from where it was placed.

Uncommon and rare side effects include:

- worsening of a mental disorder called bipolar disorder (episodes of mood swings, ranging from depressive lows to manic highs), feeling suicidal
- excessive hair growth of dark coarse hair in a male-like pattern, i.e. around mouth, chin, face, chest and back
- greasy hair

- infection of the connective tissue next to your womb, infection of the fallopian tubes or other parts of the female reproductive organs, menstrual cycle is shorter than 21 days
- swelling of the abdomen and swelling of the hands and feet.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**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 women stop having periods after 1 year of AVIBELA use. If you do not have a period for 6 weeks during AVIBELA use, call your healthcare provider. 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.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AVIBELA. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

## 5. How to store AVIBELA

Store all medicines out of reach of children.

Store at or below 30 °C.

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

Do not use after the expiry date stated on the label and the outer pack after expiry date. 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.

### The other ingredients are:

### Reservoir of the IUD

Silicone base, stannous octoate,tetra-n-propyl silicate

### T-frame

Low Density Polyethylene (LDPE), barium sulfate, Polydimethylsiloxane (PDMS) membrane, Polypropylene thread dyed with Phthalocyaninato (2-) copper.

### 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 blue 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.

AVIBELA with the inserter device is supplied partially preloaded within the inserter and packaged in a clear plastic tray with lid. AVIBELA is available in a carton of one sterile unit.

**Holder of Certificate of Registration**

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