eloira

Hormonal Intrauterine System
Levonorgestrel 52 mg.

Freedom for sure



Manufactured by:
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CLIENT INFORMATION BOOK

ELOIRA

Questions & Answers

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What is ELOIRA?

ELOIRA (Hormonal Intrauterine System) is a small device that is placed into a uterus by a doctor or nurse. It consists of a polyethylene frame which carries a matrix containing the hormone Levonorgestrel. Therefore, it is called an Intrauterine system and not just an Intrauterine device.

Eloira has two threads attached to its stem. The threads are the only part of ELOIRA that are outside the uterus and in the vagina.

The system releases Levonorgestrel into the body at a constant rate, but in very small amounts (20 micrograms/24 hrs).

How effective is ELOIRA?

The ELOIRA is a long-acting reversible method of contraception. All long acting methods are very effective because while they are being used, there is no need to remember to take or use any other contraception. In typical use the effectiveness of ELOIRA is higher than most other methods of contraception.

Chance of pregnancy during first year of use:		
Method	**Typical use**	**Perfect use**
No birth control	85%	85%
Combination pill	8%	0.30%
Progestin-only pill	13%	1.10%
Sterilization (female)	0.50%	0.50%
Sterilization (male)	0.15%	0.10%
Condom (female)	21%	5%
Condom (male)	15%	2%
Copper IUD	0.80%	0.60%
Hormone IUD	0.20%	0.20%
Lactational Amenorrhea	2%	<1%
Patch	8%	0.30%
Vaginal ring	8%	0.30%
Depo Provera	3%	0.30%
Implant	0.05%	0.05%
Diaphragm & Spermicide	16%	6%
Withdrawal	27%	4%
Standard Days Method	~12-25%	~1-9%

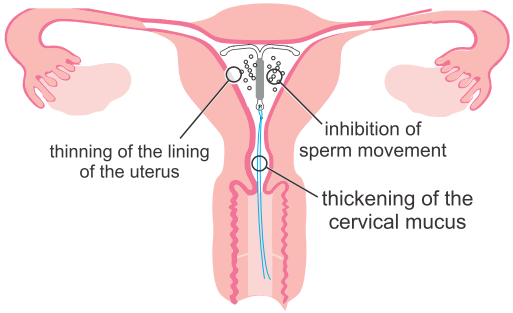
Reference: Hurt, K. Joseph, et al. (eds.); Department of Gynecology and Obstetrics, The Johns Hopkins University School of Medicine, Baltimore, Maryland (2012-03-28). The Johns Hopkins manual of gynecology and obstetrics. (4th ed.). Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins. p. 232. ISBN 978-1-60547-433-5.

When will ELOIRA start to work?

ELOIRA can be placed any time in your menstrual cycle if it is certain that you are not pregnant. It will be effective immediately on placing and starts providing protection against pregnancy.

How does ELOIRA work?

ELOIRA prevents pregnancy by making the normal mucus thicker in the cervical canal, so the sperm movement in the uterine cavity is slower which makes it difficult for the sperm to travel through the uterus to fertilize the egg. It also controls the monthly development of the lining of uterine walls. The lining will not be thick enough to support pregnancy by preventing a fertilized egg from implanting in the uterus. ELOIRA does not cause an abortion.



What are the advantages of ELOIRA?

- It works as soon as it is placed.
- It works for 5 years (but can be taken out sooner).
- It doesn't interrupt normal sexual activity.
- It can be used if you are breast feeding.
- Your fertility returns to normal as soon as ELOIRA is taken out.
- It is not affected by other medicines.
- Has a high efficacy.

What are the disadvantages of ELOIRA?

- Intermittent spotting and cramps are possible in initial few weeks, this will eventually reduce.
- Requires an internal examination to check if ELOIRA is suitable, and when it is placed.
- ELOIRA does not protect from sexually transmitted infections.

Are there any risks associated with the use of ELOIRA?

The advantage of using ELOIRA far outweigh the small risks that may be associated with the use of this device. There is a very small chance of getting an infection during the first 20 days after ELOIRA is placed. It may still be advisable to have a check up for any possible or existing infection.

ELOIRA can be pushed out by the uterus (expulsion) or it can move (displacement). This is not common. This is more likely to happen soon after it has been placed and one may not know it has happened. This is why your doctor or nurse will teach you how to check the ELOIRA threads every month.

In rare cases, ELOIRA might go through (perforate) the uterus or cervix when it is placed. This may cause pain but often there are no symptoms. If it happens, ELOIRA may have to be removed by surgery. The risk of perforation is very low when ELOIRA is placed by an experienced doctor or nurse.

If you become pregnant while you are using ELOIRA, there is a small increased risk of you having an ectopic pregnancy. The risk of ectopic pregnancy is seen less in women using ELOIRA than in women using no contraception at all.

What if I feel unwell after Eloira is placed?

If you feel unwell and have any pain in your lower abdomen, a high temperature or a smelly discharge from the vagina in the first three weeks after ELOIRA is placed, consult a doctor, or go back to the clinic as soon as possible. This could be because of possibility of having contracted an infection.

How will I know that ELOIRA is still in place?

ELOIRA has two threads attached to the end that hang a little way down from the uterus into the top of the vagina. The doctor or nurse will teach you how to feel these threads to make sure the ELOIRA is still in place. You should do this a few times in the first month and then after each period or at regular intervals. It is very unlikely that ELOIRA will come out, but if you cannot feel the threads, or if you think you can feel ELOIRA itself, you may not be protected against pregnancy. Consult your doctor or nurse immediately and use an extra contraceptive method, such as condoms. If you had sex recently, you might need to use emergency contraception. Rarely, the partner may say he can feel the threads during intercourse. If this happens, get the doctor or nurse to check the threads.

Is it safe to use tampons if I have ELOIRA placed?

Yes, you can use tampons as well as towels.

When can ELOIRA be removed?

A trained doctor or nurse can take ELOIRA out at any time, by pulling gently on the threads. If you are not going to have another ELOIRA fitted and you don't want to get pregnant, use an extra contraception, such as condoms, for seven days before ELOIRA is taken out. This is to stop the sperms getting into your body. Sperms can live for up to seven days inside your body and could cause a pregnancy once ELOIRA is removed. Your fertility returns to normal as soon as ELOIRA is taken out.

Will ELOIRA affect my periods?

You may have some light bleeding between your periods in the first six months after you have had ELOIRA placed. Some women may have heavier, longer and more painful periods. This may improve over time. If there is prolonged bleeding it

may be possible for the doctor or nurse to give appropriate treatment that can help control the bleeding. They may also check whether the bleeding is due to any other causes such as an infection.

What if I become pregnant while using ELOIRA?

Very few women become pregnant while using ELOIRA. If one does become pregnant, there is a risk of having an ectopic pregnancy. An ectopic pregnancy develops outside the uterus, usually in the fallopian tube. If you think you might be pregnant or have a sudden or unusual pain in your lower abdomen, seek medical advice as soon as possible. This might be the warning sign for an ectopic pregnancy.

If one is pregnant, ELOIRA should be removed as soon as possible, whether or not one wishes to continue with the pregnancy.

I've just had a baby. Can I use ELOIRA?

ELOIRA is usually placed from four weeks after a vaginal or caesarean birth. It can also be placed within 48 hours of birth. ELOIRA can be used safely while you are breast feeding and will not affect lactation.

How often do I need to see a doctor or nurse?

It is not necessary to have frequent checks after placing ELOIRA. One or two consultations by the doctor, done at monthly intervals after placing would normally be enough. The doctor or nurse will inform you how to check for presence of ELOIRA by feeling the threads.

However do contact your doctor or nurse if you have any problems, question or want it removed Once placed ELOIRA is effective for 5 years.

It is important to seek advice if you think you could be at risk of getting a sexually transmitted infection or symptoms mentioned below :

Pelvic Inflammatory Disease (PID)- PID is a sexually transmitted disease. You have greater chances of getting PID transmitted if you or your partner have sex with other partners. It can cause serious implications like infertility, ectopic pregnancy or constant pelvic pain. PID is treated by antibiotics. In serious cases it may require surgery.

- Consult your doctor if you have any of the following symptoms of PID: Heavy or longer bleeding, indifferent vaginal discharge, lower abdominal pain, painful sex, chills or fever.

- Consult your doctor if you have severe pain after placement of ELOIRA.

Common side effects of ELOIRA include:

- **Discomfort during placement:** Dizziness, faintness, bleeding or cramping may occur during placement. This is common. Let your healthcare provider know if the cramping is severe.

- **Expulsion:** Expulsion is when Eloira comes out by its own. You can stand the risk of getting pregnant if this happens. If you find out that Eloira has come out, use another birth control method like condoms and consult your doctor.

- **Missed menstrual periods:** Consult your doctor if you do not get your period for 6 weeks while using Eloira.

A small percentage of users may experience one or more of these effects:

- Headache/Migraine
- Acne
- Depressed mood
- Heavy or prolonged menstrual bleeding
- Vaginal discharge
- Breast pain or tenderness
- Nausea
- Nervousness
- Inflammation of cervix, vulva or vagina
- Pelvic pain during your period
- Back pain
- Weight increase
- Decreased sex drive
- High blood pressure
- Pain during intercourse
- Anaemia

- Unusual hair growth or loss
- Skin irritations (such as hives, rash, eczema or Itching)
- Feeling bloated
- Swelling of hands and/or feet
- Expulsion

In case the effects remain for a consistent longer period of time, consult your healthcare provider.

- **Changes in bleeding:** During the first 3 to 6 months, you may have bleeding and spotting in between menstrual periods. You may have unusual heavier bleeding sometimes. But mostly, the bleeding becomes lighter than usual and may get irregular. Consult your doctor if bleeding is unusual or if it becomes heavier after lighter bleeding.
- **Cyst on the ovary:** Women using ELOIRA may develop a cyst on the ovary. These cysts disappears on its own within 1 or 2 months. But, it can cause pain and may require a surgery to remove it.

Apart from the side effects mentioned, some other side effects could be there. For which you can consult your doctor.

General advice on prescription medicines: Medicines may sometimes be prescribed for certain conditions, which is not mentioned in Client information Book. The leaflets only brief the most important and critical information about ELOIRA. For any further information, talk to your doctor. You can also ask information about ELOIRA, which is provided to the doctors.

This client information booklet was last updated in March 2013.



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