

PATIENT LABELING

IMPLANON™

(etonogestrel implant)

68 mg For Subdermal Use Only

Rx only

IMPLANON™ does not protect against infection from HIV (the virus that causes AIDS) or other sexually transmitted diseases.

Read this leaflet carefully and have your healthcare provider answer all of your questions before you decide to use IMPLANON™.

What is the most important information I should know about IMPLANON™?

If IMPLANON™ is not placed properly, it may not prevent pregnancy or it may be difficult or impossible to remove. After you receive IMPLANON™, check that it is in place by pressing your fingertips over the skin in your arm where IMPLANON™ was placed. You should be able to feel the IMPLANON™ rod.

The most common side effect of IMPLANON™ is a change in your menstrual periods. Expect your menstrual period to be irregular and unpredictable throughout the time you are using IMPLANON™. You may have more bleeding, less bleeding, or no bleeding. The time between periods may vary, and in between periods you may have spotting.

What is IMPLANON™?

IMPLANON™ is a type of birth control for women. It is a flexible plastic rod the size of a matchstick that is put under the skin of your arm. IMPLANON™ contains a hormone called etonogestrel. You can use a single IMPLANON™ rod for up to three years. Because IMPLANON™ does not contain estrogen, your healthcare provider may recommend IMPLANON™ even if you cannot use estrogen.



What if I need birth control for more than three years?

You must have IMPLANON™ removed after three years. If you want to continue using IMPLANON™, your healthcare provider can put a new IMPLANON™ under your skin after taking out the old one.

What if I change my mind about birth control?

Your healthcare provider can remove IMPLANON™ at any time. If you want to become pregnant after IMPLANON™ removal, your ability to get pregnant may return quickly. If you don't want to get pregnant, you should start another birth control method right away.

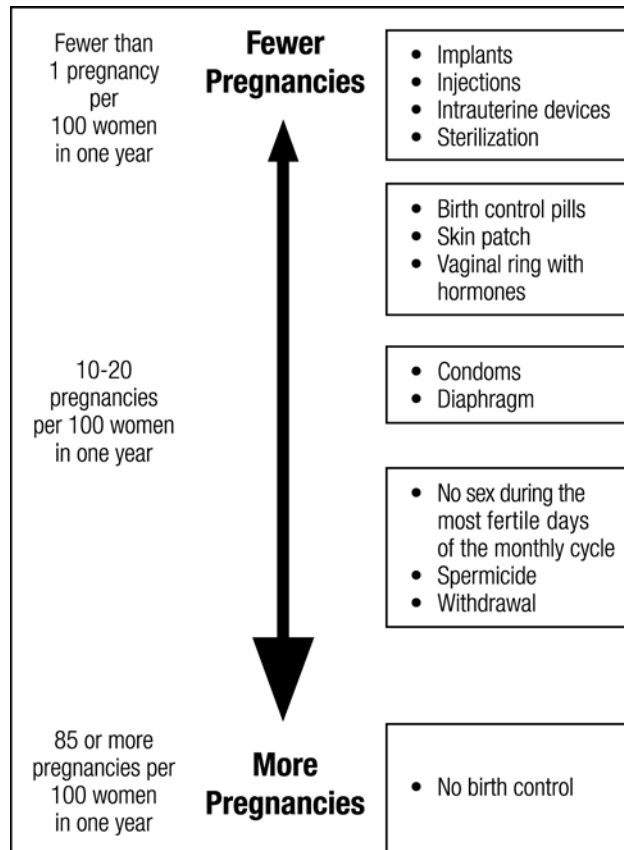
How does IMPLANON™ work?

IMPLANON™ prevents pregnancy in several ways. The most important way is by stopping release of an egg from your ovary. IMPLANON™ also changes the mucus in your cervix and this change may keep sperm from reaching the egg. Also, IMPLANON™ changes the lining of your uterus.

How well does IMPLANON™ work?

If IMPLANON™ is inserted correctly, your chance of getting pregnant is very low (less than one pregnancy per 100 women who use IMPLANON™ for one year). It is not known if IMPLANON™ is as effective in very overweight women because studies did not include many overweight women.

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.



Who should not use IMPLANON™?

Do not use IMPLANON™ if you

- Are pregnant or think you may be pregnant
- Have, or have had serious blood clots, such as blood clots in your legs (deep venous thrombosis), lungs (pulmonary embolism), eyes (retinal thrombosis), heart (heart attack), or head (stroke)
- Have unexplained vaginal bleeding
- Have liver disease
- Have breast cancer, now or in the past
- Are allergic to anything in IMPLANON™

Tell your healthcare provider if you have ever had any of the conditions just listed. Your healthcare provider can suggest another method of birth control.

In addition, talk to your healthcare provider about using IMPLANON™ if you have or had

- Diabetes
- High cholesterol or triglycerides
- Headaches
- Seizures or epilepsy
- Gallbladder or kidney disease
- Depression
- High blood pressure
- Allergic reaction to anesthetics or antiseptics. These medicines will be used when IMPLANON™ is inserted into your arm.

If you have any of these conditions, your healthcare provider can explain what to do.

How do I use IMPLANON™?

Your healthcare provider will insert (or remove) IMPLANON™ in a minor surgical procedure in his or her office. IMPLANON™ is inserted just under the skin on the inner side of your upper arm.

The timing of insertion is important. Depending on your history, your healthcare provider may ask you to

- Have a pregnancy test before insertion
- Schedule the insertion at a specific time of your cycle (for example, within the first days of your regular menstrual bleeding)
- Use a backup method of birth control, such as condoms, for seven days after IMPLANON™ insertion

Both you and your healthcare provider should check that IMPLANON™ is in your arm by feeling the IMPLANON™ implant.

If you and your healthcare provider cannot feel IMPLANON™, use a non-hormonal birth control method such as condoms until your healthcare provider confirms that IMPLANON™ is in place. You may need special tests to check that IMPLANON™ is in place or to help find IMPLANON™ when it is time to take it out.

You will be asked to review and sign a consent form prior to inserting IMPLANON™. You will also get a USER CARD to keep at home with your health records. Your healthcare provider will fill out the insertion and removal dates. Keep track of the removal date and schedule an appointment for removal with your healthcare provider on or before the removal date.

The insertion site is covered with two bandages. Leave the top bandage on for 24 hours. Keep the smaller bandage dry, clean, and in place for three to five days.

Be sure to have checkups as advised by your healthcare provider.

What are the most common side effects I can expect while using IMPLANON™?

- Irregular and Unpredictable Bleeding
The most common side effect of IMPLANON™ is a change in your menstrual periods. In studies, about one out of ten women stopped using IMPLANON™ because of bleeding problems. Expect your menstrual periods to be irregular and unpredictable throughout the time you are using IMPLANON™.

You may have more bleeding, less bleeding, or no bleeding. The time between periods may vary, and in between periods you may have spotting.

Talk with your healthcare provider if

- You think you may be pregnant
- Your vaginal bleeding is heavy and prolonged

Besides irregular bleeding, the most frequent side effects that caused women to stop using IMPLANON™ in studies were

- Mood swings
- Weight gain
- Headache
- Acne
- Depression

The most common side effects reported by women using IMPLANON™ in clinical trials were

- Irregular bleeding
- Headache
- Vaginitis (inflammation of the vagina)
- Weight gain
- Acne
- Breast pain
- Viral infections such as colds, sore throats, sinus infections, or flu-like symptoms
- Stomach pain
- Painful periods
- Mood swings, nervousness, or depression
- Back pain
- Nausea
- Dizziness
- Pain
- Pain at the site of insertion

Rare side effects that have been reported include: extra hair on your face and body, trouble using contact lenses, and spotty darkening of the skin, especially on the face. This is not a complete list of possible side effects. Talk to your healthcare provider if you have any side effects that concern you.

What are the possible risks of using IMPLANON™?

• Complications of Insertion and Removal

Rarely, removal of IMPLANON™ is difficult or even impossible because IMPLANON™ is not where it should be. If IMPLANON™ cannot be removed, then the effects of IMPLANON™ will continue for a longer period of time.

Rarely, IMPLANON™ is not inserted at all due to a failed insertion, or the implant has fallen out of the needle, and then you may become pregnant. After insertion, and with direction from your healthcare

provider, you should be able to feel IMPLANON™ under your skin. If you can't feel IMPLANON™, tell your healthcare provider.

Some other problems related to insertion and removal are

- Pain, irritation, swelling, or bruising
- Scarring, including a thick scar called a keloid
- Infection
- IMPLANON™ breaks making it difficult to remove IMPLANON™
- Thick scar tissue forming around IMPLANON™ making removal difficult
- Rarely, expulsion of the implant
- Rarely, need for surgery in the hospital for removal of IMPLANON™
- Removals of deeply inserted implants can lead to scarring or complications

• **Ectopic Pregnancy**

If you become pregnant while using IMPLANON™, you have a slightly higher chance that the pregnancy will be ectopic (occurring outside the womb) than do women who are not using birth control. Ectopic pregnancies can cause serious internal bleeding and even death.

• **Interaction with Other Medicines**

Certain medicines may make IMPLANON™ less effective and you may need to use back-up non-hormone birth control. Tell your healthcare provider about any medicines you are taking, or intend to take, including over-the-counter medicines and prescription medicines such as: barbiturates, griseofulvin, rifampin, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, and modafinil. Herbal remedies such as St. John's Wort may also reduce the effectiveness of contraceptive drug products. This is not a complete list of drugs that may interact with IMPLANON™.

When you are using IMPLANON™, tell all of your healthcare providers that you have IMPLANON™.

• **Ovarian Cysts**

Cysts on the ovaries usually go away without treatment. Sometimes surgery is needed.

• **Breast Cancer**

It is not known whether IMPLANON™ changes a woman's risk for breast cancer. If you have breast cancer now, or have had it in the past, do not use IMPLANON™ because some breast cancers are sensitive to hormones.

• **Blood Clots (Thrombosis)**

It is not known whether IMPLANON™ changes a woman's risk for serious blood clots called thrombosis. Thrombosis is a side effect of birth control pills and pregnancy. Because IMPLANON™ contains one of the two hormones that are in birth control pills, thrombosis may be a side effect of IMPLANON™. There have been post-marketing reports of thrombosis among IMPLANON™ users.

Some examples of thrombosis are

- Legs (deep vein thrombosis)
- Lung (pulmonary embolism)
- Brain (stroke)
- Heart (heart attack)
- Eyes (blindness)

The risk of thrombosis is increased in women who smoke. If you smoke, you should quit. Your healthcare provider may be able to help.

Tell your healthcare provider at least four weeks before if you are going to have surgery or will need to be on bed rest. You have an increased chance of getting thrombosis during surgery or bed rest.

- **Other Risks**

A few women who use birth control that contains hormones may get

- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

When should I call my healthcare provider?

Call your healthcare provider right away if you get any of the symptoms listed below. They may be signs of a serious problem.

- Sharp chest pain, coughing blood, or sudden shortness of breath (possible clot in the lung)
- Persistent pain in the calf (back of lower leg) (possible clot in the leg)
- Crushing chest pain or heaviness in the chest (possible heart attack)
- Sudden severe headache or vomiting, dizziness or fainting, problems with vision or speech, weakness, or numbness in an arm or leg (possible stroke)
- Sudden partial or complete blindness (possible clot in the eye)
- Yellowing of the skin or whites of the eyes (jaundice), especially with fever, tiredness, loss of appetite, dark colored urine, or light colored bowel movements (possible liver problems)
- Severe pain, swelling, or tenderness in the abdomen (possibly indicating an ectopic pregnancy, a ruptured or twisted ovarian follicle, or gallbladder or liver problems)
- Breast lumps
- Difficulty in sleeping, weakness, lack of energy, tiredness, or sadness (possible severe depression)
- Heavy vaginal bleeding

What if I become pregnant while using IMPLANON™?

You should see your healthcare provider right away. It is important to remove IMPLANON™ and make sure that the pregnancy is not ectopic (occurring outside the womb). Based on experience with birth control pills, IMPLANON™ is not likely to cause birth defects.

Can I use IMPLANON™ when I am breast feeding?

Based on a small study, you may start IMPLANON™ if you are breast feeding and if you delivered your baby more than four weeks ago. A small amount of the active substance of IMPLANON™ passes into the breast milk. The health of breast fed children whose mothers were using IMPLANON™ has been studied up to three years of age in a small number of children. No effects on the growth and development of the children were seen. If you are breast feeding and want to use IMPLANON™, talk with your healthcare provider.

What if I want to become pregnant or want to stop using IMPLANON™ for another reason before three years?

Your healthcare provider can remove IMPLANON™ at any time with a minor surgical procedure in the office. The information on your USER CARD may help your healthcare provider find IMPLANON™.

After removal, keep the removal site clean, dry, and bandaged for three to five days to lessen the chance of infection.

If you want to become pregnant, your ability to get pregnant usually returns quickly. Some women have become pregnant within days after removal of IMPLANON™. **If you do not want to become pregnant, you should start another birth control method right away.**

Additional Information

This leaflet contains important information about IMPLANON™. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about IMPLANON™ that is written for healthcare providers. You may also call 1-877-IMPLANON (1-877-467-5266) or visit www.IMPLANON-USA.com



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PATIENT CONSENT FORM

I understand the Patient Labeling for IMPLANON™. I have discussed IMPLANON™ with my healthcare provider who answered all my questions. I understand that there are benefits as well as risks from using IMPLANON™. I understand that there are other birth-control methods and that each has its own benefits and risks.

I also understand that this Patient Consent Form is important. I understand that I need to sign this form to show that I am making an informed and careful decision to use IMPLANON™, and that I have read and understand the following points.

- IMPLANON™ helps to keep me from getting pregnant.
- No contraceptive method is 100% effective, including IMPLANON™.
- IMPLANON™ is made of a hormone mixed in a plastic rod.
- It is important to have IMPLANON™ inserted at the right time of my menstrual cycle.
- **After IMPLANON™ is inserted, I should check that it is in place by gently pressing my fingertips over the skin in my arm where IMPLANON™ was inserted. I should be able to feel the small rod.**
- IMPLANON™ must be removed at the end of three years. IMPLANON™ can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove IMPLANON™, I can call 1-877-IMPLANON (1-877-467-5266) for help.
- IMPLANON™ is placed under the skin of my arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- Removal is usually a small office procedure. However, removal may be difficult. Rarely, IMPLANON™ cannot be found when it is time to remove it. Special procedures, including surgery in the hospital, may be needed. Difficult removals may cause pain and scarring. If IMPLANON™ cannot be found, its effects may continue.
- **Most women have changes in their menstrual bleeding while using IMPLANON™. I also will likely have changes in my menstrual bleeding while using IMPLANON™. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should see my healthcare provider as soon as possible.**
- I understand the warning signs for problems with IMPLANON™. I should seek medical attention if any warning signs appear.
- I should tell all my healthcare providers that I am using IMPLANON™.
- I need to have a medical checkup regularly and at any time I am having problems.
- IMPLANON™ does not protect me from HIV infection (AIDS) or any other sexually-transmitted disease.

After learning about IMPLANON™, I choose to use IMPLANON™.

Name of Healthcare Provider

Patient Signature

Date

WITNESSED BY: The patient above has signed this consent in my presence after I counseled her and answered her questions.

Healthcare Provider Signature

Date

I have provided an accurate translation of this information to the patient whose signature appears above. She has stated that she understands the information and has had an opportunity to have her questions answered.

Signature of Translator

Date