

Consumer Medicine Information

What is in this leaflet

This leaflet provides information that may help you in your decision to start using Implanon NXT. It will also advise you how to use Implanon NXT properly and safely. It answers some common questions about Implanon NXT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you using Implanon NXT against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully before you decide to have Implanon NXT inserted.

Keep this leaflet.

You may need to read it again. It is important to stay alert on matters that do not affect you now, but may affect you in the future.

What Implanon NXT is used for?

What does it contain?

Implanon NXT is a contraceptive implant preloaded in a disposable applicator. The implant contains 68 mg of the active substance etonogestrel. Etonogestrel is a synthetic female hormone resembling progesterone. A small amount of the hormone etonogestrel is continuously released into the bloodstream for three years. The rod itself is made of ethylene vinyl acetate copolymer, a plastic that will not dissolve in the body. It also contains small amounts of barium sulfate (which renders it visible under X-ray) and magnesium stearate.

Although the implant may be removed at any time, it must be removed no later than three years after insertion.

How does Implanon NXT work?

Implanon NXT is used to prevent pregnancy. Implanon NXT is placed directly under the skin at the inner side of the non-dominant upper arm.

Implanon NXT prevents pregnancy in two ways:

- It prevents the release of an egg cell from the ovaries (ovulation)
- It causes changes to cervical mucus that makes it difficult for sperm to enter the womb.

As a result, Implanon NXT protects you against pregnancy for a period of three years, but if you are overweight the doctor may advise you to replace the implant earlier. Implanon NXT is one of several means of preventing pregnancy. Another frequently used birth control method is the combined Pill. Implanon NXT differs from combined Pills in that it contains no oestrogen and you do not have to remember to take a pill every day.

Implanon NXT has several important advantages:

- It is one of the most reliable birth control methods (over 99% effective).
- It does not interfere with having sex.

- Once you stop using it you can expect your previous fertility to return quickly.

Furthermore, compared to the combined Pill, Implanon NXT has some additional advantages, but also some disadvantages:

Advantages

- You do not have to worry about taking a tablet each day; the implant should be replaced every 3 years.
- Implanon NXT may be used by women who do not tolerate oestrogens.
- In some circumstances Implanon NXT may be used by breast-feeding women. Check with your doctor for advice.

Disadvantages

- Your menstrual bleeding may change and become absent, irregular, infrequent, frequent, prolonged, or rarely heavy. The bleeding pattern that you experience during the first three months generally indicates your future bleeding pattern. (see also 'Menstrual bleeding')
- On rare occasions, the implant moves from its original position. This may complicate removal (see also 'Insertion and removal related events').
- If in rare cases the implant is not inserted correctly or is not inserted at all, you may not be protected against pregnancy.
- Implanon NXT must be inserted and removed by a doctor. A small scar may remain.

A doctor's prescription is required to obtain this medicine.

Before you have Implanon NXT inserted or removed, confirm that your doctor is familiar with the technique. For uncomplicated removals, it is necessary that Implanon NXT be inserted directly under the skin. Incorrect insertion may lead to complicated removals that may result in scarring.

Ability to drive

There are no indications of any effect of Implanon NXT on alertness and concentration.

Before you have Implanon NXT inserted

When you must not use it

Do not use Implanon NXT if you have any of the conditions listed below. If any of these apply to you, tell your doctor BEFORE Implanon NXT is inserted. Your doctor can tell you whether Implanon NXT is suitable for you or not and may advise you to use a non-hormonal method of birth control.

- If you are pregnant or think you might be pregnant
- If you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel [e.g. in the legs (deep venous thrombosis) or in the lungs (pulmonary embolism)].
- If you have or have had jaundice (yellowing of the skin), or severe liver disease, or a liver tumour.

- If you have (had) cancer or may have cancer of the breast or of the genital organs.
- If you have any unexplained vaginal bleeding.
- If you have or suspect you have cancer of the breast, ovary or womb.
- If you have benign or malignant liver tumours.
- If you are allergic to any of the ingredients of Implanon NXT; see list of ingredients at the end of this leaflet.

If any of these conditions appear for the first time while using Implanon NXT, tell your doctor immediately.

Do not use Implanon NXT if the expiry date printed on the pack has passed.

Do not use Implanon NXT if the packaging is torn or shows signs of tampering.

General notes

If you are concerned about contracting a sexually transmitted infection (STI), ask your partner to wear a condom when having sexual intercourse with you.

As with all contraceptive medicines, Implanon NXT does not protect against HIV infection (AIDS) or any other sexually transmissible infection. Only condoms and safe sex practices can protect you from these diseases. Your doctor may suggest the additional use of condoms in certain circumstances to reduce risk of such transmission.

Before you start with Implanon NXT

You must tell your doctor or family planning counsellor if you have any of the conditions listed below. You may need to be kept under close observation. Your doctor can explain this to you.

Tell your doctor if:

- you have had breast cancer.
- you have or have had a liver disease.
- you have ever had a thrombosis.
- you have diabetes.
- you are overweight.
- you have high cholesterol or triglycerides
- you suffer from epilepsy.
- you suffer from tuberculosis.
- you have high blood pressure.
- you have or have had Chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so avoid too much exposure to the sun or ultraviolet radiation.

Tell your doctor if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones:

- jaundice or itching.
- gallstone formation.
- porphyria (metabolic disease).
- systemic lupus erythematosus (SLE), a disease affecting the skin all over the body).
- haemolytic uraemic syndrome (HUS), a disorder of blood coagulation causing failure of the kidneys.

- Sydenham's chorea (a neurological disease).
- Herpes gestationis.
- hearing loss.

Hormonal contraceptives and cancer

Breast cancer has been found slightly more often in women using oral combined pills, but it is not known whether this is caused by the treatment. For example, it may be that tumours are found more in women on combined pills, because they are examined by the doctor more often. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill.

It is important to regularly check your breasts and you should contact your doctor if you feel any lump in your breasts.

You should also tell your doctor if a close relative has or ever had breast cancer.

In rare cases, benign and even more rarely malignant liver tumours have been reported in women using the Pill.

If you experience severe abdominal pain, you should contact your doctor immediately.

This information has been obtained in studies with women who daily take an oral combined contraceptive Pill. It is not known whether these observations are also applicable to women who use a different hormonal contraceptive, such as implants containing only a progestagen.

Hormonal contraceptives and thrombosis

Thrombosis is the formation of a blood clot. A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins in the leg (deep venous thrombosis, DVT), the lung (a lung embolus), or other organs. A blood clot in an artery (known as 'arterial thrombosis') can block the artery. For example, a blood clot in an artery may cause a heart attack, or in the brain may cause a stroke.

Using any combined hormonal contraceptive increases a woman's risk of developing such clots compared with a woman not taking any combined hormonal contraceptive. The risk is not as high as the risk of developing a blood clot during pregnancy. There have been reports of blood clot formation like lung emboli, deep vein thrombosis, heart attacks and strokes in women using etonogestrel implants. The risk with progestagen-only methods like Implanon NXT is believed to be lower than in users of pills that also contain oestrogens.

If you notice any signs of a thrombosis, you should see a doctor immediately (see 'While you are using Implanon NXT' for symptoms of thrombosis).

Menstrual bleeding

Like with other progestagen-only contraceptives, your menstrual bleeding pattern may change when using Implanon NXT. You may experience a change in frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or in duration. Absence of bleeding was reported in about 1 of 5 women while another 1 of 5 women reported frequent and/or prolonged bleeding. Occasionally

heavy bleeding has been observed. In clinical trials, bleeding changes were the most common reason for stopping treatment (about 11 %). The bleeding pattern that you experience during the first three months generally indicates your future bleeding pattern.

A changing bleeding pattern does not mean that Implanon NXT does not suit you or is not giving you contraceptive protection. In general, you do not need to take any action. You should consult your doctor if menstrual bleeding is heavy or prolonged. It is important to have regular medical check ups, because while irregular bleeding is a common side effect of Implanon NXT, it may rarely be caused by other medical conditions.

Insertion and removal related events

The implant may move from the original insertion site in the arm, if incorrectly inserted or due to external forces (e.g. manipulation of the implant or contact sports). In these cases localisation of the implant may be more difficult and removal may require a larger incision. If the implant cannot be found, and there is no evidence it has been expelled, contraception and the risk of progestagen-related undesirable effects may last longer than you want.

In rare cases implants have been found in the pulmonary artery (a blood vessel in the lung). If the implant cannot be found in the arm your healthcare professional may use x-rays or other imaging methods on the chest. If the implant is located in the chest, surgery may be needed.

Broken or bent implant

If the implant breaks or bends while in your arm, how the implant works should not be affected. Breakage or bending may occur due to external forces (e.g. manipulation of the implant or contact sports). The broken implant may move from the insertion site. If you have questions, contact your healthcare provider.

Ovarian cysts

During the use of all low-dose hormonal contraceptives, small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own. Sometimes they cause mild abdominal pain. Only rarely, they may lead to more serious problems.

Ectopic pregnancy

Ectopic pregnancy is a pregnancy outside the womb. Because Implanon NXT effectively protects you against pregnancy for 3 years it can also protect you against having a pregnancy outside the womb, but this effect is not as good as with the combined Pill. Failure to remove (and if appropriate reinsert Implanon NXT) after 3 years may increase your risk of an ectopic pregnancy.

Implanon NXT and pregnancy

Tell your doctor immediately if you are pregnant or think you are pregnant while you are using Implanon NXT.

Implanon NXT must not be used by women who are pregnant, or who think they may be pregnant. In case you doubt whether you are pregnant or not, you should perform a pregnancy test before starting to use Implanon NXT.

Implanon NXT and breastfeeding

Implanon NXT may be used while you are breastfeeding. Although a small amount of the active substance of Implanon NXT passes into the breast milk, there is no effect on the production or the quality of breast milk, nor on the growth and development of the child.

If you are breastfeeding and want to use Implanon NXT, you should contact your doctor.

Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines or herbal products you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may stop Implanon NXT from working properly. These include:

- medicines for epilepsy (such as primidone, phenytoin, barbiturates, carbamazepine, oxycarbamazepine, topiramate, felbamate)
- medicines for tuberculosis (e.g. rifampicin and rifabutin)
- medicines for HIV infection (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
- medicines for hepatitis C virus infection (e.g. boceprevir, telaprevir)
- medicines for high blood pressure in the blood vessels of the lungs (bosentan)
- medicines for other infectious disease (e.g. griseofulvin)
- medicines for depressive moods (the herbal remedy containing St. John's wort).

Implanon NXT may also interfere with the working of other medicines; e.g. increase the activity of ciclosporin and decrease the effect of lamotrigine.

You should tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you are using Implanon NXT. If you are taking medicines or herbal products that might make Implanon NXT less effective, you and your doctor may decide to leave Implanon NXT in place; in that case, an additional non-hormonal contraceptive (such as a condom or cap plus spermicide) should be used. Since the effect of another medicine on Implanon NXT may last up to 28 days after stopping the medicine, it is necessary to use the additional non-hormonal contraceptive for that long.

When should you contact your doctor?

Regular check ups

Before Implanon NXT is inserted, your healthcare professional will ask you some questions about your personal health history and that of your close relatives. The healthcare professional will also measure your blood pressure, and depending on your personal situation, may also carry out some other tests. When you are using Implanon NXT, your doctor will tell you to return for regular check-ups. The frequency and nature of these check-ups will depend on your personal situation but should occur at least every year.

Consult your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also 'When you must not use it' and 'Before you start with Implanon NXT'); do not forget about the items related to your immediate family.
- you notice possible signs of a thrombosis such as severe pain or swelling in either of your legs, breathlessness, an unusual cough, especially if you cough up blood.
- you have a sudden, severe stomach-ache or yellowing of the skin (indicating possible liver problems).
- you feel a lump in your breast (see also 'Hormonal contraceptives and cancer').
- you feel sudden or severe pain in the lower abdomen or stomach area.
- you have unusual, heavy vaginal bleeding.
- you are to be immobilised or are to have surgery; tell your doctor at least 4 weeks in advance.
- you suspect that you are pregnant.

How should Implanon NXT be used?

How should Implanon NXT be inserted and removed?

Tell your doctor if you are pregnant or think you might be pregnant before Implanon NXT is inserted (e.g. if you had unprotected sex during your current menstrual cycle).

Implanon NXT should only be inserted and removed by a doctor who is familiar with the technique.

The doctor will decide in consultation with you the most suitable time for insertion. This depends on your personal situation (e.g. on the birth control method that you are currently using). Unless you are switching from another hormonal contraceptive method, insertion should be done on day 1-5 of your normal menstrual bleeding to rule out pregnancy. If the implant is placed after the fifth day of menses then you should use an additional contraceptive method (such as a condom) for the first 7 days after insertion.

Before inserting or removing Implanon NXT, your healthcare professional will give you a local anaesthetic. Implanon NXT is inserted directly under the skin, on the inside of your upper non-dominant arm (the arm that you do not write with). The insertion of Implanon NXT is not generally painful if performed with a local anaesthetic and only takes the time required for an injection.

At the end of the insertion procedure, the healthcare professional will ask you to palpate the implant (feel the implant under your skin). A correctly inserted implant should be clearly palpable by the healthcare professional as well as by you, and you should be able to feel both ends between your thumb and finger. It should be realised that palpation is not suitable for 100% verification of the presence of the implant. If the implant cannot be palpated immediately after insertion, or at any time, the implant may not have been inserted, or it may have been inserted deeply. In case of the slightest doubt you have to use a barrier method (e.g. a condom) until the healthcare professional

and you are absolutely sure that the implant has been inserted. The healthcare professional may have to use X-rays, ultrasound or magnetic resonance imaging, or may have to take a blood sample, to make sure that the implant is inside your arm. Once the healthcare professional has located the implant that was not palpable, it should be removed.

If the implant cannot be found in the arm after a thorough search, your healthcare professional may use X-rays or other imaging methods on your chest.

To help you remember when and where Implanon NXT was inserted, and when Implanon NXT must be removed at the latest, your healthcare professional will give you a User Card that shows this information. Store the card in a safe place!

In case you would like to have Implanon NXT replaced, a new implant may be inserted immediately after the old implant is removed. The new implant may be inserted in the same arm and at the same site as the previous implant, as long as the site is in the correct location. Your healthcare professional will advise you.

You should avoid playing with the rod after insertion to prevent it from moving from its original position.

Implanon NXT should be removed or replaced no later than three years after insertion.

Failure to do so may increase your risk of ectopic pregnancy.

Removal requires a small incision under local anaesthetic. Occasionally removal may be complicated because the rod was inserted too deeply, moved from its original position, or broke while in the arm.

When to insert Implanon NXT

No additional contraception is necessary when Implanon NXT is inserted at the right time in your cycle.

No preceding hormonal contraceptive use

Implanon NXT should be inserted on day 1-5 of your natural cycle (day 1 being the first day of menstrual bleeding) even if the woman is still bleeding.

Changing from a combined oral contraceptive (COC)

The implant should be inserted preferably on the day after the last active tablet (the last tablet containing the active substances) of the previous COC, but at the latest on the day following the usual tablet-free or placebo tablet interval of the previous COC. In case a vaginal ring or transdermal patch has been used, the implant should be inserted preferably on the day of removal, but at the latest when the next application would have been due.

Changing from a progestagen-only method (progestagen-only pill, injectable, implant, or intrauterine system [IUS])

As there are several types of progestagen-only methods, the insertion of the implant must be performed as follows:

- Injectable contraceptives: Insert the implant on the day the next injection is due.

- Progestagen-only pill: A woman may switch from the progestagen-only pill to Implanon NXT on any day. The implant should be inserted within 24 hours after taking the last tablet.
- Implant/Intrauterine system (IUS): Insert the implant on the same day the previous implant or IUS is removed.

Following birth, miscarriage or abortion

Consult your doctor or Family Planning adviser before insertion of Implanon NXT.

It is important to follow the directions above regarding the proper timing of the insertion of Implanon NXT.

If inserted as recommended, back-up contraception is not necessary. If deviating from the above directions, pregnancy should be first ruled out and you should use a non-hormonal contraceptive method, such as condoms, until 7 days after insertion of the implant.

If you want to stop using Implanon NXT

You can ask your healthcare professional to remove the implant at any time you want.

If your implant is not easy to feel under the skin, removal should be performed by someone who is skilled in removal of deeply inserted Implanon NXT. If the implant cannot be localised by palpation, the healthcare professional may use X-rays, ultrasound or magnetic resonance imaging to locate the implant. If these imaging methods fail to locate the implant, your healthcare professional may check the etonogestrel levels of your blood for verification of the presence of the implant. Depending on the exact position of the implant removal may be difficult and may require surgery.

If you do not wish to get pregnant, you should start using another reliable birth control method on the same day that Implanon NXT is removed. Ask your doctor for advice.

If you stop using Implanon NXT because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

While you are using Implanon NXT

When you are using Implanon NXT, you should arrange for regular check-ups by your doctor. He or she should pay special attention to your blood pressure and your breasts and give you a regular examination of the pelvic organs (including a cervical smear).

Consult your doctor promptly if any of the following happen:

If you have any of the signs of a blood clot, as below:

- Sudden severe pain in the chest, whether it reaches to the arm or not.
- If you suddenly become breathless.
- If you suddenly lose vision, partially or completely, or if you see double.
- If you have an unusual, severe or prolonged headache.
- If your speech is abnormal.
- If you experience dizziness.

- If you have a fainting attack or you collapse.
- If one side or part of your body suddenly becomes very weak or numb.
- If you suffer severe pain in one of your calves.

Side Effects of Implanon NXT

Various undesirable effects that have been associated with the hormones used for birth control are similar to those that may occur during pregnancy. The reason for this is the similarity between these hormones and the natural hormones produced in extra large amounts during pregnancy. These effects can also occur during the use of Implanon NXT but are not necessarily caused by it.

Tell your doctor or pharmacist as soon as possible if you do not feel well while using it.

Like all medicines, Implanon NXT can have side effects. Sometimes they are serious, most of the time they are not.

Serious side effects

Serious reactions associated with the use of Implanon NXT, as well related symptoms, are described in the following sections:

'Before you have Implanon NXT inserted', 'Hormonal contraceptives and thrombosis', 'Hormonal contraceptives and cancer'.

Please read the following sections for additional information and consult your doctor at once where appropriate.

Other possible side effects

- acne
- headache
- breast tenderness and pain
- weight gain
- irregular bleeding
- hair loss
- dizziness
- depression
- emotional lability or mood swings
- nervousness
- libido decreased
- abdominal pain
- nausea
- gas in stomach and intestines
- painful menstruation
- implant site pain and/or reaction
- itching
- vomiting

Apart from these side effects, a rise in blood pressure has occasionally been observed. Also oily skin has been observed.

You should see your doctor immediately if you experience symptoms of a severe allergic reaction such as:

1. swollen face, tongue or throat;
2. trouble swallowing; or
3. hives and trouble breathing.

Insertion and removal related effects

During the insertion or removal of Implanon NXT, some vasovagal reactions (for example: drop in blood pressure, dizziness, or fainting), bruising, pain, swelling or itching and in rare cases infection may occur.

Occasionally, fibrous tissue may appear at the implantation site, or a scar or abscess will be formed. Rarely, numb feeling or sensation of numbness (or lack of feeling) may occur.

Expulsion or migration of Implanon NXT is possible, especially if the implant has not been inserted properly. Surgery might be necessary when removing Implanon NXT. In rare cases, implants have been reported to be found in a blood vessel, including a blood vessel in the lung, which can be associated with symptoms such as shortness of breath, cough and/or the coughing up of blood or blood-stained mucus.

Tell your doctor or family planning counsellor if any side effect becomes troublesome or continues. It is also important to tell them if you experience any other unusual or unexpected symptoms during the use of Implanon NXT.

After using Implanon NXT

Storage

Store Implanon NXT in a cool dry place where the temperature stays below 30°C.

Do not use after the expiry date stated on the blister and outer box.

Your doctor will not use Implanon NXT after the expiry date, which is the last date for insertion.

Do not use Implanon NXT if the packaging is worn or torn, or if the product does not look quite right.

Do not open the sterile plastic box containing the applicator.

Disposal

Your doctor will arrange disposal of Implanon NXT upon removal of the old implant.

Product Description

What it looks like

Implanon NXT consists of a radiopaque progestagen-only implant preloaded in a disposable applicator. The off-white implant is 4 cm in length and 2 mm in diameter.

Do not be alarmed by the size of the box or the applicator.

Ingredients

Active substance

- 68 mg etonogestrel

Other ingredients

- Ethylene vinyl acetate copolymer (a type of plastic): Evatane 28-25RG (proprietary ingredient 139830)
- Ethylene vinyl acetate copolymer (a type of plastic): Evatane 1040VN4 (proprietary ingredient 139829)
- Barium sulfate
- Magnesium stearate

Supplier

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