

Package leaflet: Information for the user

Implanon NXT®, 68mg implant for subdermal use (etonogestrel)

Your medicine is available using the above name but will be referred to as Implanon NXT throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Implanon NXT is and what it is used for
- What you need to know before you use Implanon NXT
- How to use Implanon NXT
- Possible side effects
- How to store Implanon NXT
- Contents of the pack and other information

1. WHAT IMPLANON NXT IS AND WHAT IT IS USED FOR

Implanon NXT is a contraceptive implant preloaded in a disposable applicator for women 18 to 40 years of age. The implant is a small, soft, flexible, plastic rod, 4cm in length and 2mm in diameter, which contains 68 milligrams of the active substance, etonogestrel. The applicator allows the healthcare professional to insert the implant just under the skin of your upper arm. Etonogestrel is a synthetic female hormone resembling progesterone. A small amount of etonogestrel is continuously released into the bloodstream. The implant itself is made of ethylene vinyl acetate copolymer, a plastic that will not dissolve in the body. It also contains a small amount of barium sulfate which renders it visible under X-ray.

Implanon NXT is used to prevent pregnancy.

How does Implanon NXT work

The implant is inserted just below the skin. The active compound, etonogestrel, works in two ways:

- It prevents the release of an egg cell from the ovaries.
- It causes changes in the cervix that make 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. In contrast to combined Pills, Implanon NXT can be used by women who may not, or do not want to use oestrogens. When you use Implanon NXT you do not have to remember to take a pill every day. This is one of the reasons that Implanon NXT is very reliable (over 99% effective). If in rare cases the implant is not inserted correctly or is not inserted at all, you may not be protected against pregnancy. When you are using Implanon NXT, 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. Painful periods may improve.

You may stop using Implanon NXT at any time (See also “When you want to stop using Implanon NXT”).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE IMPLANON NXT
Hormonal contraceptives, also including Implanon NXT, do not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Implanon NXT

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

- if you are allergic to etonogestrel or any of the other ingredients of this medicine (listed in section 6).
- if you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel [for example in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)].
- if you have or have had jaundice (yellowing of the skin), severe liver disease (when the liver is not functioning properly), or a liver tumour.
- if you have (had) or if you may have cancer of the breast or of the genital organs.
- if you have any unexplained vaginal bleeding.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Implanon NXT.

If Implanon NXT is used in the presence of any of the conditions listed below, you may need to be kept under close observation. Your doctor can explain to you what to do. If any of these apply to you, tell your doctor before Implanon NXT is inserted. Also if the condition develops or gets worse while you are using Implanon NXT you must tell your doctor.

- you have had cancer of the breast;
- you have or have had a liver disease;
- you have ever had a thrombosis;
- you have diabetes;
- you are overweight;
- 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.

Possible serious conditions

Cancer

The information presented below has been obtained in studies with women who daily take an oral combined contraceptive containing two different female hormones (“the 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.

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. The increased occurrence of breast cancer becomes gradually less after stopping the combined 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.

Thrombosis

A blood clot in a vein (known as a ‘venous thrombosis’) can block the vein. This can happen in veins in the leg, 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. The risk with progestagen-only methods like Implanon NXT, is believed to be lower than in users of Pills that also contain oestrogens. There have been reports of blood clot formation like lung emboli, deep vein thrombosis, heart attacks and strokes in women using etonogestrel implants; however, available data do not suggest an increase in risk of these events in women using the implant.

If you suddenly notice possible signs of a thrombosis, you should see your doctor immediately. (See also “When should you contact your doctor”?).

Other conditions

Menstrual bleeding pattern changes

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 frequent, 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.

Insertion and removal related events

The implant may migrate 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 rare cases implants have been found in the blood vessels of the arm or in the pulmonary artery (a blood vessel in the lung). In cases where the implant has migrated from the original insertion site, localization of the implant may be more difficult and removal may require a larger incision or surgical removal in the hospital. 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.

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.

If at any time the implant cannot be felt, it should be found and removal may be recommended.

Psychiatric disorders

Some women using hormonal contraceptives including Implanon NXT have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

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.

Broken or bent implant

If the implant breaks or bends while in your arm, how the implant works should not be affected. If you have questions, contact your healthcare provider.

Other medicines and Implanon NXT

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Implanon NXT. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines

- can have an influence on the blood levels of Implanon NXT
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include medicines used for the treatment of

- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate),
- tuberculosis (e.g. rifampicin),
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz),
- Hepatitis C Virus infection (e.g. boceprevir, telaprevir),
- other infectious diseases (e.g. griseofulvin),
- high blood pressure in the blood vessels of the lungs (bosentan),
- depressive moods (the herbal remedy St. John’s wort (*Hypericum perforatum*)).

Implanon NXT may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Ask your doctor or pharmacist for advice before taking any medicine.

Implanon NXT with food and drink

There are no indications of any effect of food and drink on the use of Implanon NXT.

Pregnancy and breast-feeding

You must not use Implanon NXT if you are pregnant, or think you may be pregnant. In case you doubt whether you are pregnant or not, you should perform a pregnancy test before starting using Implanon NXT.

Implanon NXT may be used while you are breast-feeding. Although a small amount of the active substance of Implanon NXT passes over 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 breast-feeding, ask your doctor for advice before using this medicine.

Children and adolescents

The safety and efficacy of Implanon NXT in adolescents under the age of 18 have not been studied.

Driving and using machines

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

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 healthcare professional may ask you to return for a (routine) medical check-up some time after insertion of the implant. The frequency and nature of further check-ups will depend on your personal situation.

Contact 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 “Do not use Implanon NXT” and “Warnings and precautions”; do not forget about the items related to your immediate family);
- you notice possible signs of thrombosis such as severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood;
- you have a sudden, severe stomach ache or look jaundiced;
- you feel a lump in your breast (see also “Cancer”);
- you have a sudden or severe pain in the lower part of your belly or stomach;
- you have unusual, heavy vaginal bleeding;
- you are to be immobilised (for example being confined to bed) or are to have surgery (consult your doctor at least four weeks in advance);
- you suspect that you are pregnant.

3. HOW TO USE IMPLANON NXT

Please tell your healthcare professional if you are pregnant or think you might be pregnant before Implanon NXT is inserted (e.g. if you had unprotected intercourse during the current menstrual cycle).

How to use

Implanon NXT should be inserted and removed only by a healthcare professional who is familiar with procedures as described on the other side of this leaflet. The healthcare professional will decide in consultation with you the most suitable time for insertion. This depends on your personal situation (for example on the birth control method that you are currently using). Unless you are switching from another hormonal contraceptive method, the insertion should be performed on day 1-5 of your spontaneous menstrual bleeding to rule out pregnancy. Your healthcare professional will advise you (for more information see section 7.1).

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). A description of the insertion and the removal procedure of Implanon NXT is shown in section 6.

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

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!

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. 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. Once the healthcare professional has located the implant that was not palpable, your healthcare professional may recommend removal based on your health needs.

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. Your healthcare professional will advise you.

When you want to stop using Implanon NXT

You can ask your healthcare professional to remove the implant at any time you want. If the implant cannot be localised by palpation, the healthcare professional may use X-rays, ultrasound or magnetic resonance imaging to locate the implant. Depending on the exact position of the implant removal may be difficult and may require surgery.

If you do not want to become pregnant after removal of Implanon NXT, ask your healthcare professional about other reliable methods of birth control. 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Implanon NXT can cause side effects, although not everybody gets them.

Menstrual bleeding may occur at irregular intervals during the use of Implanon NXT. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Implanon NXT is decreased. In general, you need not take any action. If, however, bleeding is heavy or prolonged consult your doctor.

Serious undesirable effects are described in the paragraphs of section 2 “Cancer” and “Thrombosis”. Please read this section for additional information and consult your doctor at once where appropriate.

The following side effects have been reported:

Very Common (may affect more than 1 in 10 people)	Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)
acne; headache; increase in body weight; breast tenderness and pain; irregular bleeding; infection of the vagina.	hair loss; dizziness; depressive moods; emotional lability; nervousness; decreased sexual drive; increased appetite; abdominal pain; nausea; gas in stomach and intestines; painful menstruation; decrease in body weight; influenza-like symptoms; pain; fatigue; hot flushes; implant site pain; implant site reaction; ovarian cyst.	itching; itching in the genital area; rash; excessive hair growth; migraine; anxiety; sleeplessness; sleepiness; diarrhoea; vomiting; constipation; urinary tract infection; vaginal discomfort (e.g. vaginal secretion); breast enlargement; breast secretion; back pain; fever; fluid retention; difficult or painful urination; allergic reactions; inflammation and pain of the throat; rhinitis; joint pain; muscle pain; skeletal pain.

Apart from these side effects, a rise in blood pressure has occasionally been observed. Also oily skin has been observed. You should seek immediate medical attention if you experience symptoms of a severe allergic reaction, such as (i) swollen face, tongue or pharynx; (ii) trouble swallowing; or (iii) hives and trouble breathing.

During the insertion or removal of Implanon NXT, some bruising, pain, swelling, or itching may occur and, in rare cases, infection. A scar may be formed or an abscess may develop at the implantation site. A numb feeling or sensation of numbness (or lack of feeling) may occur. Expulsion or migration of the implant is possible, especially if it has not been inserted properly. In rare cases, implants have been reported to be found in a blood vessel, including a blood vessel in the lung. Surgery might be necessary when removing the implant.

There have been reports of blood clot in a vein (known as a ‘venous thrombosis’) or in an artery (known as ‘arterial thrombosis’) in women using etonogestrel implant. A blood clot in a vein can block the vein, and can happen in veins in the leg (a deep vein thrombosis), the lung (a lung embolus), or other organs. A blood clot in an artery can block the artery and may cause a heart attack, or in the brain may cause a stroke.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

5. HOW TO STORE IMPLANON NXT

Keep this medicine out of the sight and reach of children.

Store in the original blister package. Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month. For single use only. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Implanon NXT contains

Each implant contains 68mg of the active substance etonogestrel. The other ingredients are: ethylene vinyl acetate copolymer, barium sulfate and magnesium stearate.

What Implanon NXT looks like and contents of the pack

Implanon NXT is a subdermal long acting hormonal contraceptive. It consists of a radiopaque progestagen-only implant preloaded in an innovative, ready-for-use, user-friendly, disposable applicator. The off-white implant is 4cm in length and 2mm in diameter and contains etonogestrel and barium sulfate. The applicator has been designed to facilitate the insertion of the implant just below the skin of your inner upper (non-dominant) arm. The implant is to be inserted and removed by a healthcare professional who is familiar with the procedures. For uncomplicated removal it is necessary that the implant is inserted just below the skin (see other side of the leaflet). Local anaesthetic should be used before inserting or removing the implant. The risk of complications is small if the provided instructions are followed.

The pack contains one implant for subdermal use in the cannula of a disposable sterile applicator.

Manufacturer

Implanon NXT is manufactured by:
N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA1151/094/001

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Germany, Greece, Ireland, Luxembourg, Malta, the Netherlands, Slovakia, Poland, Portugal, Spain: Implanon NXT
Denmark, Estonia, Finland, France, Iceland, Italy, Norway, Romania, Sweden, UK: Nexplanon

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

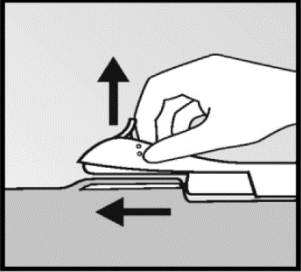
These pictograms are only meant to illustrate the insertion and removal procedures for the woman who will be receiving the implant.

Note: The exact procedures for the insertion and removal of Implanon NXT by the qualified healthcare professional are described in the Summary of Product Characteristics and in section 7 of this user package leaflet.

6.1 HOW IS IMPLANON NXT INSERTED

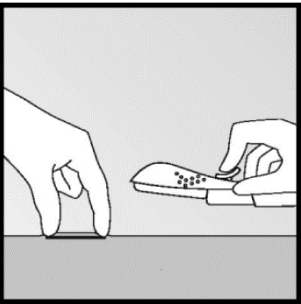
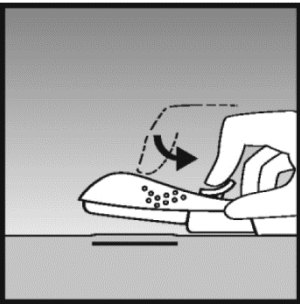


- Insertion of Implanon NXT should only be performed by a qualified healthcare professional who is familiar with the procedure.
- To facilitate the insertion of the implant, you should lie on your back, with your arm slightly bent at the elbow and turned outwards.



- The implant will be inserted at the inner side of your upper non-dominant arm (the arm that you do not write with).
- The insertion site will be indicated on the skin, the site is disinfected and anaesthetised.

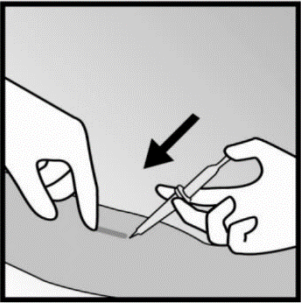
- The skin is stretched and the needle is inserted, **directly** under the skin. Once the tip is inside the skin the needle is completely inserted in a movement parallel to the skin.



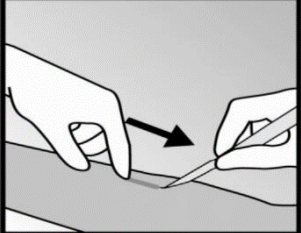
- The purple slider is unlocked by pushing it slightly down and fully pushing it backwards until it is arrested in the back in order to retract the needle. The implant will remain in the upper arm when the needle is withdrawn.
- **The presence of the implant should be verified by feeling it (palpation) immediately following insertion. A correctly inserted implant can be felt between thumb and finger by both the healthcare professional and by you. It should be realised that palpation is not suitable for 100% verification of the presence of the implant.**
- **In case the implant cannot be palpated or when its presence is doubtful other methods must be used to confirm the presence of the implant.**
- **Once the healthcare professional has located the implant that was not palpable, your healthcare professional may recommend removal based on your health needs.**
- **Until the presence of the implant has been verified you may not be protected against pregnancy and a contraceptive barrier method (e.g. condoms) must be used.**
- You will be given sterile gauze with a pressure bandage to minimise bruising. You may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.
- After insertion of the implant, the healthcare professional will give you a User Card with on it the insertion site, insertion date and the latest date on which the implant has to be removed or replaced. Put it in a safe place, since the information on the card may facilitate removal later on.

6.2 HOW SHOULD IMPLANON NXT BE REMOVED

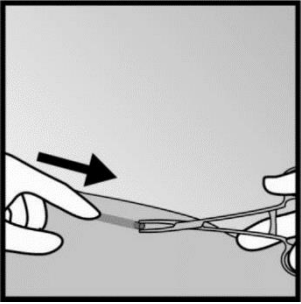
- The implant should only be removed by a qualified healthcare professional who is familiar with the procedure.
- The implant is removed at your request or – **at the latest – three years after insertion.**
- The location of the insertion site of the implant is indicated on the User Card.
- The healthcare professional will locate the implant. If the implant cannot be located the healthcare professional may have to use X-ray, CT, ultrasound or magnetic resonance imaging techniques.



- Your upper arm will be disinfected and anaesthetised.



- A small incision will be made along the arm just below the tip of the implant.



- The implant is gently pushed towards the incision and removed with forceps.

- Occasionally, the implant may be surrounded by hard tissue. If this is the case, a small cut needs to be made into the tissue before the implant can be removed.
- If you want your healthcare professional to replace Implanon NXT with another implant, the new implant may be inserted using the same incision.
- The incision will be closed by a steri-strip.
- You will be given sterile gauze with a pressure bandage to minimise bruising. You may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.