Package leaflet: Information for the user

Nexplanon® 68 mg implant for subdermal use
etonogestrel

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.

Your doctor will give you a Patient Alert Card that contains important information you need to be aware of. Store the card in a safe place, and show it to your healthcare professional at any visits related to the use of your implant.

What is in this leaflet

1. What Nexplanon is and what it is used for

Nexplanon is a contraceptive implant preloaded in a disposable applicator. Safety and efficacy have been established in women between 18 and 40 years of age. The implant is a small, soft, flexible, plastic rod, 4 cm in length and 2 mm 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 sulphate which renders it visible under X-ray.

Nexplanon is used to prevent pregnancy.

How does Nexplanon 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, Nexplanon 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. Nexplanon is one of several means of preventing pregnancy. Another frequently used birth control method is the combined Pill. In contrast to combined Pills, Nexplanon can be used by women who may not, or do not want to use oestrogens. When you use Nexplanon you do not have to remember to take a pill

every day. This is one of the reasons that Nexplanon 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 Nexplanon, 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 Nexplanon at any time (see also "*When you want to stop using Nexplanon"*).

2. What you need to know before you use Nexplanon

Hormonal contraceptives, also including Nexplanon, do not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Nexplanon
Do not use Nexplanon if you have any of the conditions listed below. If any of these conditions apply to you, tell your doctor before Nexplanon 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 Nexplanon, consult your doctor immediately.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Nexplanon.

If Nexplanon 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 Nexplanon is inserted. Also if the condition develops or gets worse while you are using Nexplanon 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 Nexplanon, 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 Nexplanon. 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 Nexplanon 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 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 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, localisation 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, **you should contact your doctor as soon as possible**.

Psychiatric disorders
Some women using hormonal contraceptives including Nexplanon 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. Breakage or bending may occur due to external forces. The broken implant may move from the insertion site. If you have questions, contact your healthcare provider.

Other medicines and Nexplanon

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 Nexplanon. 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 Nexplanon
- 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*)).

Nexplanon may influence the effect of other medicines, e.g.
- medicines containing ciclosporin
- the anti-epileptic (this could lead to an increased frequency of seizures)

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

Nexplanon with food and drink
There are no indications of any effect of food and drink on the use of Nexplanon.

Pregnancy and breast-feeding
You must not use Nexplanon 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 Nexplanon.

Nexplanon may be used while you are breast-feeding. Although a small amount of the active substance of Nexplanon 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 Nexplanon 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 Nexplanon on alertness and concentration.

When should you contact your doctor?
Regular check-ups
Before Nexplanon 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 Nexplanon, your healthcare professional may ask you to return for a (routine) medical check-up sometime after insertion of the implant. The frequency and nature of further check-ups will depend on your personal situation. Your healthcare professional should palpate the implant at each check-up visit.

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 Nexplanon" 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;**
- **the implant is not palpable after insertion or at any time.**

3. How to use Nexplanon

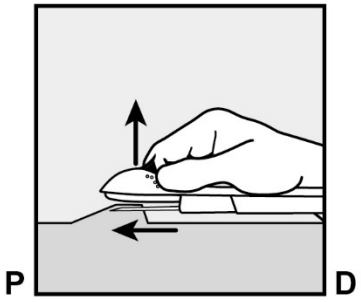
Please tell your healthcare professional if you are pregnant or think you might be pregnant before Nexplanon is inserted (e.g. if you had unprotected sex during the current menstrual cycle).

How to use
Nexplanon 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. 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 Nexplanon, your healthcare professional will give you a local anaesthetic. Nexplanon 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 Nexplanon is shown below.

How is Nexplanon inserted

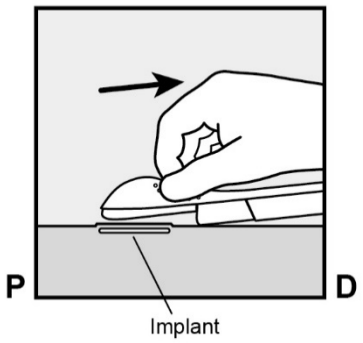
- **Insertion of Nexplanon should only be performed by a qualified healthcare professional who is familiar with the procedure.**
- **To facilitate the insertion of the implant, you should lie on your back, with your arm bent at the elbow and with your hand underneath your head (or as close as possible).**

- **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, and 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.**

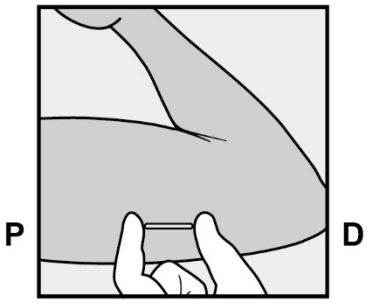


P, proximal (toward the shoulder);
D, distal (toward the elbow)

- **The purple slider is unlocked 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, it should be removed.**
- **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.**
- A small adhesive bandage will be placed over the insertion site and a pressure bandage will be placed to minimise bruising. You may remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site in 3-5 days.
- After insertion of the implant, the healthcare professional will give you a Patient Alert 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.

The implant must be palpable after insertion

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, may have been inserted deeply, or may have migrated from the place it was inserted.

Therefore, it is important to occasionally gently palpate the implant to be sure that you know its location. If at any time you cannot feel the implant, contact your doctor as soon as possible.

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, it should be removed.

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

Patient Alert Card
To help you remember when and where Nexplanon was inserted, and when Nexplanon must be removed at the latest, your healthcare professional will give you a Patient Alert Card that shows this information. The Patient Alert Card also contains instructions to occasionally gently palpate the implant to be sure that you know its location. If at any time you cannot feel the implant, contact your doctor as soon as possible. Store the card in a safe place! Show the Patient Alert Card to your healthcare professional at any visits related to the use of your implant.
In case you would like to have Nexplanon 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.

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

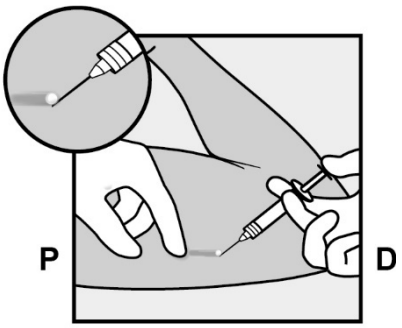
If the implant cannot be localised by palpation, the healthcare professional may use X-rays, ultrasound or magnetic resonance imaging to locate the implant. Depending on the exact position of the implant removal may be difficult and may require surgery.

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

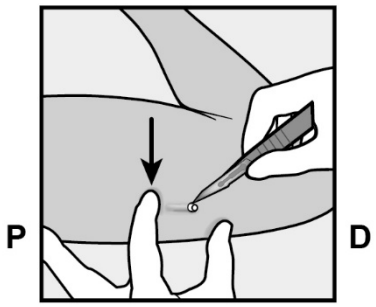
If you stop using Nexplanon because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

How should Nexplanon 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 Patient Alert 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.**

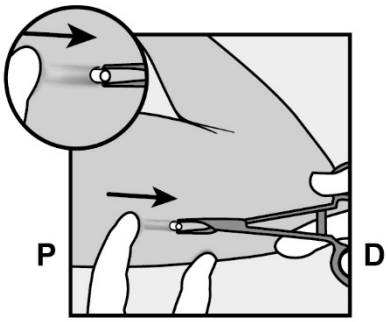
- To facilitate the removal of the implant, you should lie on your back, with your arm bent at the elbow and with your hand underneath your head (or as close as possible).



- 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 a 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 Nexplanon with another implant, the new implant may be inserted using the same incision as long as the site is in the correct location.**
- **The incision will be closed by a sterile adhesive wound closure.**
- **A pressure bandage will be placed to minimise bruising. You may remove the pressure bandage in 24 hours and the sterile adhesive wound closure over the insertion site in 3-5 days.**

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 Nexplanon by the qualified healthcare professional are described in the Summary of product characteristics and in section 7 on the other side of this user package leaflet.

4. Possible side effects

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

Menstrual bleeding may occur at irregular intervals during the use of Nexplanon. 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 Nexplanon 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 • breasts 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. Increased pressure in your head (*benign intracranial hypertension*) with signs as lasting headache, along with feeling sick (*nausea*), being sick (*vomiting*) and change in your eyesight including blurred vision has been reported. 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 Nexplanon, some bruising (severe in some cases), 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. Due to insertion of the implant you might feel faint. 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, which can be associated with shortness of breath and/or cough with or without bleeding. 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.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nexplanon

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

Do not use this medicine after the expiry date which is stated on the blister and carton.

Store in the original blister package.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.
This medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

What Nexplanon contains
Each applicator contains one implant with
- The active substance is: etonogestrel (68 mg)
- The other ingredients are: ethylene vinyl acetate copolymer, barium sulphate and magnesium stearate.

What Nexplanon looks like and contents of the pack
Nexplanon 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 4 cm in length and 2 mm in diameter and contains etonogestrel and barium sulphate. 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.

Pack sizes: Carton box with 1 blister pack, carton box with 5 blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Organon Pharma (UK) Limited, Shotton Lane, Cramlington, United Kingdom, NE23 3JU.

Manufacturer
N.V. Organon, Kloosterstraat 6, 5349 AB Oss,
The Netherlands

This leaflet was last revised in October 2024.

PIL.NEX.23.UK.0213.II-IPP_IPA.RCN003122

Nexplanon®
68 mg implant for subdermal use
Etonogestrel

Information for the healthcare professional

The following information is intended for the *healthcare professionals only:*

Insertion of Nexplanon should be performed under aseptic conditions, and only by a physician or healthcare professional who is familiar with the procedure, those who have completed (or are participating under supervision in) a training programme such as that leading to a letter of Competence in subdermal contraceptive implants offered by the Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists.

7. Information for the healthcare professional

7.1 When to insert Nexplanon

IMPORTANT: Rule out pregnancy before inserting the implant.

Timing of insertion depends on the woman's recent contraceptive history, as follows:

No preceding hormonal contraceptive use in the past month:
The implant should be inserted between Day 1 (first day of menstrual bleeding) and Day 5 of the menstrual cycle, even if the woman is still bleeding.

If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

Switching hormonal contraceptive method to Nexplanon
Changing from a combined hormonal contraceptive method (combined oral contraceptive (COC), vaginal ring or transdermal patch).
The implant should be inserted preferably on the day after the last active tablet (the last tablet containing the active substances) of the previous combined oral contraceptive or on the day of removal of the vaginal ring or transdermal patch. At the latest, the implant should be inserted on the day following the usual tablet-free, ring free, patch free or placebo tablet interval of the previous combined hormonal contraceptive when the next application would have been due. Not all contraceptive methods (transdermal patch, vaginal ring) may be available in all countries.

If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

Changing from a progestagen-only contraceptive method (e.g. 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 Nexplanon on any day of the month. 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.**

If inserted as recommended, back up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

Following abortion or miscarriage
The implant can be inserted immediately following abortion or miscarriage.
- First trimester: If inserted within 5 days, back-up contraception is not necessary.
- Second trimester: If inserted within 21 days, back-up contraception is not necessary.

If inserted after the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded before insertion.

Following postpartum
The implant can be inserted immediately postpartum in both breast-feeding and non-breast-feeding women, based on an individual benefit/risk assessment.
- If inserted within 21 days, back up contraception is not necessary.
- If inserted after 21 days postpartum, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded before insertion.

7.2 How to insert Nexplanon
The basis for successful use and subsequent removal of Nexplanon is a correct and carefully performed subdermal insertion of the implant in the non-dominant arm in accordance with the instructions. Both the HCP and the woman should be able to feel the implant under the woman's skin after placement.

The implant should be inserted subdermally just under the skin at the inner side of the non-dominant upper arm.
- An implant inserted more deeply than subdermally (deep insertion) may not be palpable and the localisation and/or removal can be difficult (see section 4.2 How to remove Nexplanon and section 4.4 in the SmPC).
- If the implant is inserted deeply, neural or vascular damage may occur. Deep or incorrect insertions have been associated with paraesthesia (due to neural damage) and migration of the implant (due to intramuscular or fascial insertion), and in rare cases with intravascular insertion.

Insertion of Nexplanon should be performed under aseptic conditions and only by a qualified HCP who is familiar with the procedure. Insertion of the implant should only be performed with the preloaded applicator.

Insertion Procedure

To help make sure the implant is inserted just under the skin, the HCP should be positioned to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view the insertion site and the movement of the needle just under the skin can be clearly seen from the side visualised.

For illustrative purposes, Figures depict the left inner arm.

- Have the woman lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her hand is underneath her head (or as close as possible) (Figure 1).

Figure 1

- **Identify the insertion site, which is at the inner side of the non-dominant upper arm. The insertion site is overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to (below) the sulcus (groove) between the biceps and triceps muscles (Figures 2a, 2b and 2c). This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. If it is not possible to insert the implant in this location (e.g. in women within thin arms) it should be inserted as far posterior from the sulcus as possible.**

- Make two marks with a surgical marker: first, mark the spot where the implant will be inserted, and second, mark a spot at 5 centimetres (2 inches) proximal (toward the shoulder) to the first mark (Figure 2a and 2b). This second mark (guiding mark) will later serve as a direction guide during insertion.

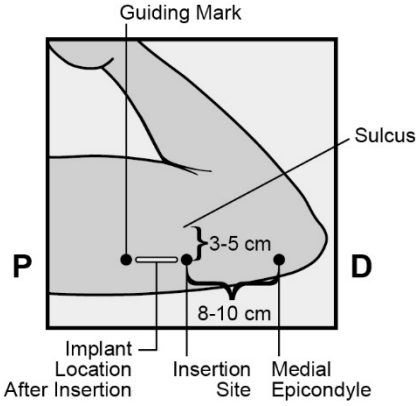


Figure 2a

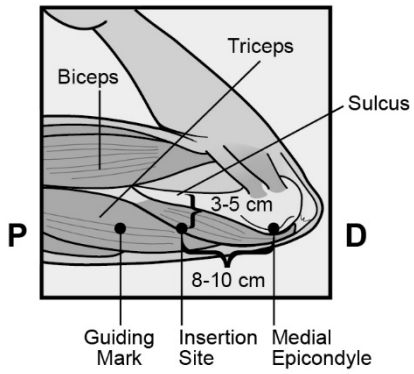


Figure 2b

P - Proximal (toward the shoulder);
D - Distal (toward the elbow)

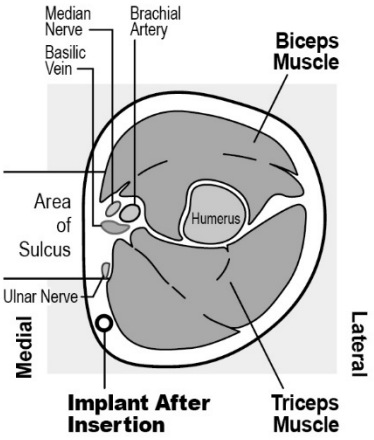


Figure 2c
Cross section of the upper left arm,
as viewed from the elbow
Medial (inner side of the arm)
Lateral (outer side of the arm)

- **After marking the arm, confirm the site is in the correct location on the inner side of the arm.**
- **Clean the skin from the insertion site to the guiding mark with an antiseptic solution.**
- **Anaesthetise the insertion area (for example, with anaesthetic spray or by injecting 2 ml of 1 % lidocaine just under the skin along the planned insertion tunnel).**
- **Remove the sterile preloaded disposable Nexplanon applicator carrying the implant from its blister. Inspect for breaches of packaging integrity prior to use by a visual check for damages (e.g. torn, punctured, etc). If the packaging has any visual damage that could compromise sterility, do not use the applicator.**

- Hold the applicator just above the needle at the textured surface area. Remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle (Figure 3). If the cap does not come off easily the applicator should not be used. You should see the white coloured implant by looking into the tip of the needle. **Do not touch the purple slider until you have fully inserted the needle subdermally, as doing so will retract the needle and prematurely release the implant from the applicator.**
- If the purple slider is released prematurely, restart the procedure with a new applicator.

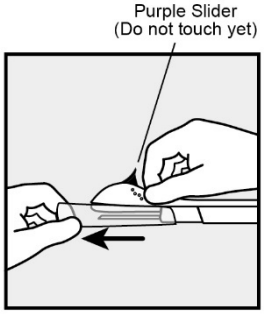


Figure 3

- With your free hand, stretch the skin around the insertion site towards the elbow (Figure 4).

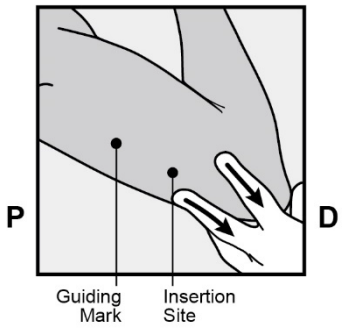


Figure 4

- **The implant should be inserted subdermally just under the skin** (see section 4.4 in the SmPC).
  To help make sure the implant is inserted just under the skin, you should position yourself to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view you can clearly see the insertion site and the movement of the needle just under the skin (see Figure 6).

- Puncture the skin with the tip of the needle slightly angled less than 30° (Figure 5a).

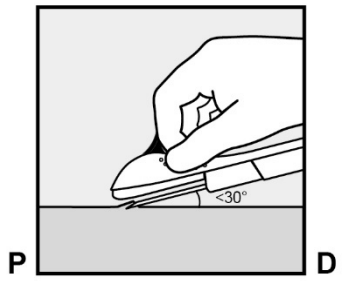


Figure 5a

- Insert the needle until the bevel (slanted opening of the tip) is just under the skin (and no further) (Figure 5b). If you inserted the needle deeper than the bevel, withdraw the needle until only the bevel is beneath the skin.

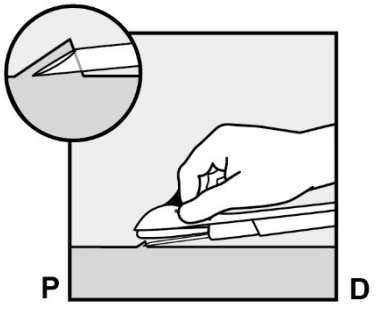


Figure 5b

- Lower the applicator to a nearly horizontal position. To facilitate subdermal placement lift the skin with the needle, while sliding the needle to its full length (Figure 6). You may feel slight resistance but do not exert excessive force. **If the needle is not inserted to its full length, the implant will not be inserted properly.**

  If the needle tip emerges from the skin before needle insertion is complete, the needle should be pulled back and be readjusted to subdermal position to further complete the insertion procedure.

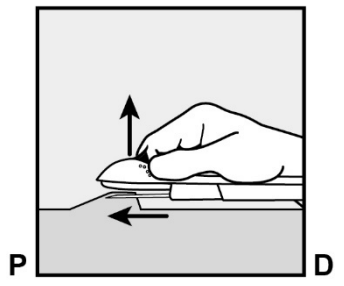


Figure 6

- Keep the applicator in the same position with the needle inserted to its full length (Figure 7). If needed, you may use your freehand to stabilise the applicator.

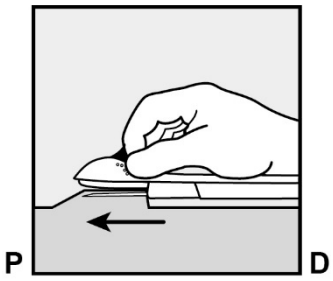


Figure 7

- Unlock the purple slider by pushing it slightly down (Figure 8a). Move the slider fully back until it stops. **Do not move (⃠) the applicator while moving the purple slider** (Figure 8b). The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator. The applicator can now be removed (Figure 8c).

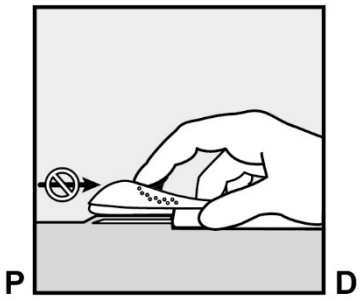


Figure 8a

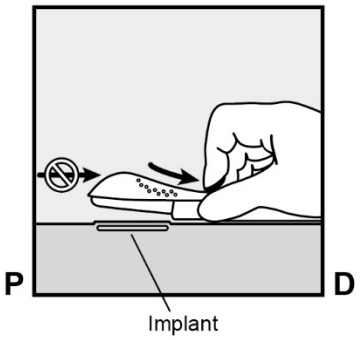


Figure 8b

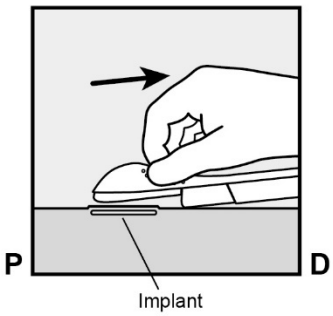


Figure 8c

If the applicator is not kept in the same position during this procedure or if the purple slider is not moved fully back until it stops, the implant will not be inserted properly and may protrude from the insertion site.

If the implant is protruding from the insertion site, remove the implant and perform a new procedure at the same insertion site using a new applicator. **Do not push the protruding implant back into the incision.**

- Apply a small adhesive bandage over the insertion site.

- **Always verify the presence of the implant in the woman's arm immediately after insertion by palpation.** By palpating both ends of the implant, you should be able to confirm the presence of the 4 cm rod (Figure 9). See section below "If the implant is not palpable after insertion".

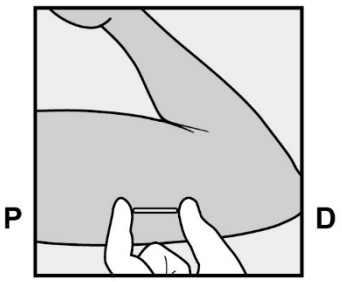


Figure 9

- **Request that the woman palpate the implant.**
- **Apply sterile gauze with a pressure bandage to minimise bruising. The woman may remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site after 3-5 days.**
- **Complete the Patient Alert Card and give it to the woman to keep. Also, complete the adhesive labels and affix it to the woman's medical record. If electronic patient records are used, the information on the adhesive label should be recorded.**
- **The applicator is for single use only and must be adequately disposed of, in accordance with local regulations for the handling of biohazardous waste.**

If the implant is not palpable after insertion:

If you cannot palpate the implant or are in doubt of its presence, the implant may not have been inserted or it may have been inserted deeply:

- **Check the applicator. The needle should be fully retracted and only the purple tip of the obturator should be visible.**
- **Use other methods to confirm its presence. Given the radiopaque nature of the implant, suitable methods for localisation are two-dimensional X-ray and X-ray computerised tomography (CT scan). Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater) or magnetic resonance imaging (MRI) may be used. In case the implant cannot be found with these imaging methods, it is advised to verify the presence of the implant by measuring the etonogestrel level in a blood sample from the woman. In this case, contact the local representative of the Marketing Authorisation Holder who will provide the appropriate protocol.**
- **Until you have verified the presence of the implant, a non-hormonal contraceptive method must be used.**
- **Deeply placed implants should be localised and removed as soon as possible to avoid the potential for distant migration (see section 4.4 in the SmPC).**

7.3 How to remove Nexplanon

Removal of the implant should only be performed under aseptic conditions by an HCP who is familiar with the removal technique. **If you are unfamiliar with the removal technique, contact the local representative of the Marketing Authorisation Holder: Organon Pharma (UK) Limited. Telephone: 0208 1593593**, **medicalinformationuk@organon.com for further information.**

Before initiating the removal procedure, the HCP should assess the location of the implant. Verify the exact location of the implant in the arm by palpation.

If the implant is not palpable, consult the Patient Alert Card or medical record to verify the arm which contains the implant. If the implant cannot be palpated, it may be deeply located or have migrated. Consider that it may lie close to vessels and nerves. Removal of non-palpable implants should only be performed by an HCP experienced in removing deeply placed implants and familiar with localising the implant and the anatomy of the arm. Contact the local representative of the Marketing Authorisation Holder office: Organon Pharma (UK) Limited. Telephone: 0208 1593593, medicalinformationuk@organon.com for further information.
See section below on “Localisation and removal of a non-palpable implant” if the implant cannot be palpated.

Procedure for removal of an implant that is palpable

For illustrative purposes, Figures depict the left inner arm

- Have the woman lie on her back on the table. The arm should be positioned with the elbow flexed and the hand underneath the head (or as close as possible). (See Figure 10)

Figure 10

- Locate the implant by palpation. Push down the end of the implant closest to the shoulder (Figure 11) to stabilise it; a bulge should appear indicating the tip of the implant that is closest to the elbow**. If the tip does not pop up, removal of the implant may be difficult** and should be performed by providers experienced with removing deeper implants. Contact the local representative of the Marketing Authorisation Holder: Organon Pharma (UK) Limited. Telephone: 0208 1593593, medicalinformationuk@organon.com for further information.
- Mark the distal end (end closest to the elbow), for example, with a surgical marker.
- Clean the site where the incision will be made with an antiseptic solution.

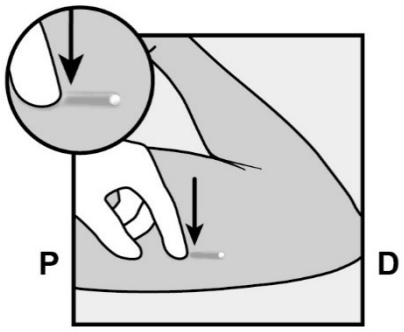


Figure 11
P, proximal (toward the shoulder);
D, distal (toward the elbow)

- Anaesthetise the site, for example, with 0.5 to 1 ml 1 % lidocaine where the incision will be made (Figure 12). Be sure to inject the local anaesthetic **under** the implant to keep it close to the skin surface. Injection of local anaesthetic over the implant can make removal more difficult.

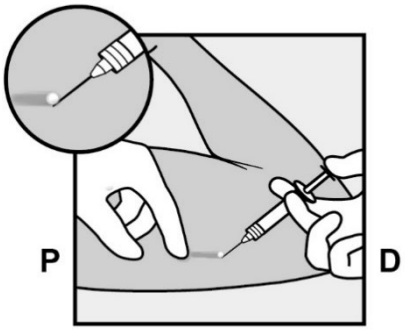


Figure 12

- Push down the end of the implant closest to the shoulder (Figure 13) to stabilise it throughout the procedure. Starting over the tip of the implant closest to the elbow, make a longitudinal (parallel to the implant) incision of 2 mm towards the elbow. Take care not to cut the tip of the implant.

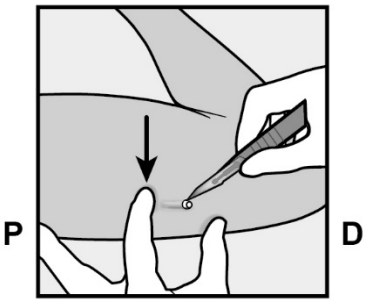


Figure 13

- The tip of the implant should pop out of the incision. If it does not gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps if possible and remove the implant (Figure 14).
- If needed, gently remove adherent tissue from the tip of the implant using blunt dissection. If the implant tip is not exposed following blunt dissection, make an incision into the tissue sheath and then remove the implant with the forceps (Figures 15 and 16).

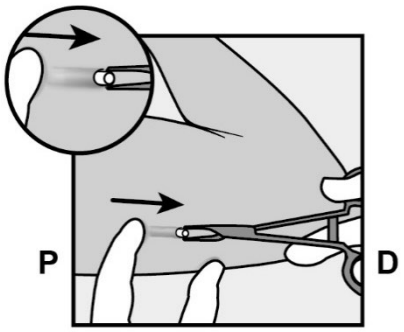


Figure 14

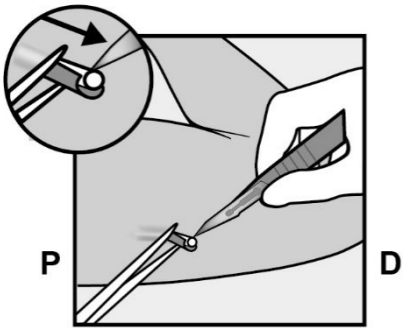


Figure 15

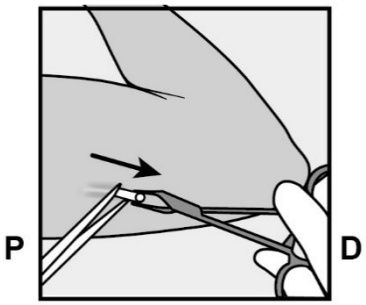


Figure 16

- If the tip of the implant does not become visible in the incision, gently insert a forceps (preferably curved mosquito forceps, with the tips pointed up) superficially into the incision (Figure 17).
- Gently grasp the implant and then flip the forceps over into your other hand (Figure 18).
- With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant (Figure 19). The implant can then be removed.
- **If the implant cannot be grasped, stop the procedure and refer the woman to an HCP experienced with complex removals or contact the local representative of the Marketing Authorisation Holder: Organon Pharma (UK) Limited. Telephone: 0208 1593593**, **medicalinformationuk@organon.com.**

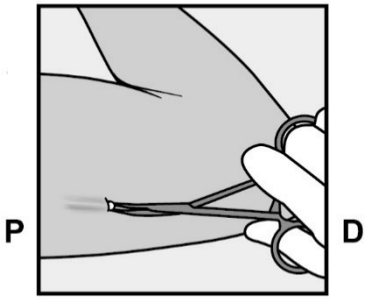


Figure 17

Figure 18

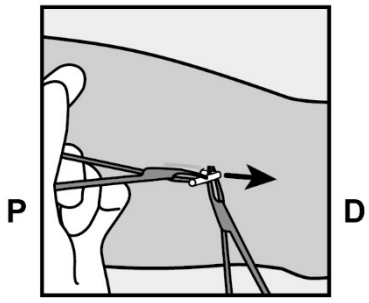


Figure 19

- **Confirm that the entire rod, which is 4 cm long, has been removed by measuring its length. There have been reports of broken implants while in the patient's arm. In some cases, difficult removal of the broken implant has been reported. If a partial implant (less than 4 cm) is removed, the remaining piece should be removed by following the instructions in this section.**
- **If the woman would like to continue using Nexplanon, a new implant may be inserted immediately after the old implant is removed using the same incision as long as the site is in the correct location (see section 7.4).**
- **After removing the implant, close the incision with a sterile adhesive wound closure.**
- **Apply sterile gauze with a pressure bandage to minimise bruising. The woman may remove the pressure bandage after 24 hours and the sterile adhesive wound closure after 3-5 days.**

Localisation and removal of a non-palpable implant

There have been occasional reports of migration of the implant; usually this involves minor movement relative to the original position (see also section 4.4 in the SmPC), but may lead to the implant not being palpable at the location in which it was placed. An implant that has been deeply inserted or has migrated may not be palpable and therefore imaging procedures, as described below, may be required for localisation.

A non-palpable implant should always be located prior to attempting removal. Given the radiopaque nature of the implant, suitable methods for localisation include two-dimensional X-ray and X-ray computer tomography (CT). Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater) or magnetic resonance imaging (MRI) may be used. Once the implant has been localised in the arm, the implant should be removed by an HCP experienced in removing deeply placed implants and familiar with the anatomy of the arm. The use of ultrasound guidance during the removal should be considered.

If the implant cannot be found in the arm after comprehensive localisation attempts, consider applying imaging techniques to the chest as extremely rare cases of migration to the pulmonary vasculature have been reported. If the implant is located in the chest, surgical or endovascular procedures may be needed for removal; HCPs familiar with the anatomy of the chest should be consulted.

If at any time these imaging methods fail to locate the implant, etonogestrel blood level determination can be used for verification of the presence of the implant. Please contact your local representative of the Marketing Authorisation Holder for further guidance.

If the implant migrates within the arm, removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating room. Removal of deeply inserted implants

should be conducted with caution in order to help prevent damage to deeper neural or vascular structures in the arm.

Non-palpable and deeply inserted implants should be removed by HCPs familiar with the anatomy of the arm and removal of deeply-inserted implants.

Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged.

Please contact your local representative of the Marketing Authorisation Holder for further guidance.

7.4 How to replace Nexplanon

Immediate replacement can be done after removal of the previous implant and is similar to the insertion procedure described in section 7.2.

The new implant may be inserted in the same arm, and through the same incision from which the previous implant was removed as long as the incision is in the correct location, i.e. 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to (below) the sulcus (see section 4.2 How to insert Nexplanon in the SmPC). If the same incision is being used to insert a new implant, anaesthetise the insertion site by injecting an anaesthetic (e.g. 2 ml lidocaine (1 %) just under the skin) commencing at the removal incision along the ‘insertion canal’ and follow the subsequent steps in the insertion instructions.

PIL.NEX.23.UK.0213.II-IPP_IPA.RCN003122