PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

Implanon NXT® 68 mg Implant

Read all of this leaflet carefully before Implanon NXT is inserted.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

1. WHAT Implanon NXT CONTAINS

The active substance is: etonogestrel (68 mg).

The other ingredients are: ethylene vinyl acetate copolymer, barium sulphate.

2. WHAT Implanon NXT IS USED FOR

Implanon NXT is used to prevent pregnancy.

3. BEFORE Implanon NXT IS INSERTED

Do not use Implanon NXT

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 Implanon NXT.

- If you have or have had a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel, for example in the legs (deep vein thrombosis) or the lungs (pulmonary embolism).
- If you have or have had jaundice (yellowing of the skin) or severe liver disease (when the liver is not functioning properly) or liver growth (liver cancer).
- If you have or have had, or if you may have cancer of the breast or of the genital organs.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.

Implanon NXT does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

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

Take special care with 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. If the condition develops or gets worse while you are using Implanon NXT, you must tell your doctor.

- If you have or have had cancer of the breast
- If you have or have had a liver disease
- If you have ever had a thrombosis
- If you have diabetes
- If you are overweight
- If you have high cholesterol or triglycerides
- If you suffer from epilepsy
- If you suffer from tuberculosis (TB)

- If you have high blood pressure
- If 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 pill ("the Pill"). It is not known whether these observations are also applicable to women who use Implanon NXT.

Breast cancer has been found more often in women using oral combined contraceptive pills.

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

Liver growths 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 (deep vein thrombosis), the lung (a lung embolus) or other organs. A blood clot in the 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.

There have been reports of blood clot formation like lung emboli, deep vein thrombosis, heart attacks and strokes in women using etonogestrel implants such as Implanon NXT. **If**

you notice suddenly possible signs of thrombosis, you should see your doctor immediately.

Menstrual bleeding pattern changes

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 20 % of women while another 20 % of women reported frequent and/or prolonged bleeding. Occasionally heavy bleeding has been observed. Bleeding changes were the most common reason for stopping treatment (about 11 %).

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

Implanon NXT may move from the original insertion site in the arm, if incorrectly inserted, or due to external forces (e.g. manipulation of (fiddling) with the implant or contact sport activities). Finding 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, and there is no evidence it has been expelled, contraception and the risk of progestogen-related undesirable effects may last longer than you want.

In rare cases implants have also 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.

Ovarian cysts

During the use of Implanon NXT, small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own but may cause mild abdominal pain or they may lead to more serious problems.

Other conditions

Broken or bent implant

If the implant breaks or bends while in your arm, how the implant works may be affected. If you have questions, contact your healthcare professional.

Using Implanon NXT with food and drink

Food and drink have no influence on the action of Implanon NXT.

Pregnancy and breastfeeding

Implanon NXT must not be inserted when you are pregnant or think you may be pregnant. If you are unsure whether you are pregnant or not, a pregnancy test should be done before starting using Implanon NXT.

Implanon NXT has been used in women breastfeeding their infants. Please consult with your doctor, pharmacist or other healthcare professional for advice.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using Implanon NXT.

Driving and using machinery

Do not drive or use any tools or machines if you feel tired or sleepy from the use of Implanon NXT.

Using other medicines with Implanon NXT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines may stop Implanon NXT from working properly. 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).

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

Always tell the doctor, who prescribes Implanon NXT, which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use 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 method 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.

4. HOW Implanon NXT IS USED

Please 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 the current menstrual cycle).

Implanon NXT should be inserted and removed only by your doctor who is familiar with the procedures. The medical practitioner 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 to 5 of your spontaneous (natural) menstrual bleeding to rule out pregnancy. If the implant is placed after the fifth day of menses (menstruation) then you should use an additional contraceptive method (such as a condom) for the first 7 days after insertion.

Your medical practitioner will advise you when to insert Implanon NXT.

Before inserting or removing Implanon NXT, your doctor 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).

At the end of the insertion procedure, your doctor will ask you to palpate the implant (feel the implant under the skin). A correctly inserted implant should be clearly palpable by your doctor as well as by you, and you should be able to feel both ends can be lifted between 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 too deeply. In case of the slightest doubt you have to use a condom until your doctor and you are absolutely sure that the implant has been inserted. Your doctor 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 your doctor 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 doctor may use x-rays or other imaging methods on your chest.

Implanon NXT should be removed or replaced no more than 3 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!

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 doctor will advise you.

When you stop using Implanon NXT

You can ask your medical practitioner to remove the implant at any time you want. If the implant cannot be localised by palpation, your doctor 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 doctor about other reliable methods of birth control.

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

An implant should always be removed before inserting a new one. There is no information available on overdose with etonogestrel (Implanon NXT).

If you have any further questions on the use of Implanon NXT, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

Implanon NXT can have side effects.

Not all side effects reported for Implanon NXT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Implanon NXT, please inform your doctor or pharmacist, or other healthcare professional for advice.

You should seek medical attention immediately if you experience symptoms of severe allergic reaction, such as:

- Swollen face, eyes, lips, tongue or throat
- Trouble swallowing
- Hives and difficulties to breathe.

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.

Users of Implanon NXT have reported the following side effects:

More frequent

- Acne
- Headache
- Increase in body weight
- Breast tenderness and pain
- Irregular bleeding
- Infection of the vagina.

Frequent

- Hair loss
- Dizziness
- Depressive moods
- Emotional lability
- Nervousness
- Decrease sexual drive
- Increase 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.

Less frequent

- 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
- Difficulty 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 been observed. Also, oily skin has been observed.

During the insertion or removal of Implanon NXT, bruising, pain, swelling, itching or infection may occur. A scar may be formed or an abscess (boil) 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. Surgery might be necessary when removing the implant. In rare cases, implants have been reported to be found in a blood vessel, including a blood vessel in the lung.

If any of the side effects gets serious, please tell your doctor or pharmacist.

6. STORAGE AND DISPOSING OF Implanon NXT

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use Implanon NXT after the expiry date which is stated on the blister and carton.

Implanon NXT should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

7. PRESENTATION OF Implanon NXT

One pack contains one implant which is pre-loaded in the stainless steel of a ready-to-use, disposable sterile applicator. The applicator containing the implant is packed in a blister pack made of transparent polyethyleneterephtalate glycol (PETG) sealed with a lidding made of high density polyethylene (HDPE).

8. IDENTIFICATION OF Implanon NXT

The pack contains a smooth and flexible rod of a white to slightly yellow or slightly brown colour, 4 cm in length and 2 mm in diameter, in the stainless steel needle of a ready-to-use disposable sterile applicator.

9. REGISTRATION NUMBER

34/18.8/0448

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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