

Implanon(R) implant

im-pla-non implant

Etonogestrel (*et-ono-ges-trel*)

Consumer Medicine Information

What is in this leaflet

This leaflet provides information that may help you in your decision to start using Implanon. It will also advise you how to use Implanon properly and safely. It answers some common questions about Implanon. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Implanon against the benefits they expect it will have for you.

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

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

Keep this leaflet.

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

What is Implanon and what is it used for?

What does it contain?

Implanon is a single, small semi-rigid rod, 4 cm in length and 2 mm in diameter, which contains 68 mg of the active substance Etonogestrel. A small amount of the

hormone etonogestrel is continuously released into the bloodstream for three years. The rod itself is made of ethylene vinylacetate copolymer, a plastic that will not dissolve in the body.

Although Implanon may be removed at any time, it must be removed no more than three years after insertion.

How does Implanon work?

Implanon is placed directly under the skin of the non-dominant upper arm.

Implanon is a contraceptive.

The etonogestrel in Implanon prevents pregnancy in two ways:

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

Implanon is one of several means of preventing pregnancy. Another frequently used birth control method is the combined Pill. Implanon differs from combined Pills in that it contains no oestrogen and you do not have to remember to take a pill every day.

Implanon has several important advantages:

- * It is one of the most reliable birth control methods. However, there is no birth control method that is 100% effective.
- * It does not interfere with having sex.
- * Once you stop using it you can expect your previous fertility to return quickly.

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

Advantages

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

Disadvantages

- * Vaginal bleeding may occur at irregular intervals during the use of Implanon. You also may not have any bleeding at all (see also 'Vaginal bleeding')
- * On rare occasions, Implanon moves from its original position. This may complicate removal (see also 'Insertion and removal related effects').
- * Implanon must be inserted and removed by a doctor. A small scar may remain.

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

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

Ability to drive

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

What you need to know before using and during the use of Implanon

When you must not use it

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

- * If you are pregnant or think you might be pregnant
- * If you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel [e.g. in the legs (deep venous thrombosis) or in the lungs (pulmonary embolism)]
- * If you have jaundice (yellowing of the skin) or severe liver disease
- * If you have a cancer that grows under the influence of progestagens
- * If you have any unexplained vaginal bleeding
- * If you have or suspect you have cancer of the breast, ovary or womb
- * If you have benign or malignant liver tumours
- * If you are allergic to any of the ingredients of Implanon

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

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

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

General notes

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

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

Before you start with Implanon

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

Tell your doctor if:

- * you have 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.

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

- * jaundice or itching
- * gallstone formation
- * porphyria (metabolic disease)
- * systemic lupus erythematosus (SLE, a disease affecting the skin all over the body)

- * haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys)
- * Sydenham's chorea (a neurological disease)
- * herpes gestationis
- * hearing loss

Hormonal contraceptives and breast cancer

Every woman is at risk of breast cancer whether or not she uses hormones for contraception. Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill.

This information applies to women using the combined Pill but may also apply to women using other hormonal contraceptives such as implants.

Hormonal contraceptives and thrombosis

Thrombosis is the formation of a blood clot, which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis, DVT). If the blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. As a result, fatal situations may occur. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are using hormones for contraception. Thrombosis can also happen if you become pregnant.

The risk is higher in Pill-users than in non-users. The risk with progestagen-only contraceptives like Implanon is believed to be lower than in users of Pills that also contain oestrogens (combined Pills). In any

case, the risk is not as high as the risk during pregnancy.

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

Vaginal bleeding

Vaginal bleeding may occur at irregular intervals using Implanon. This may be slight spotting which may not even require a pad, or a heavier so-called 'breakthrough' bleeding, which looks rather like a period and requires sanitary protection. You also may not have any bleeding at all. This does not mean that Implanon does not suit you or is not giving you contraceptive protection. However, you should consult your doctor if vaginal bleeding is heavy or prolonged.

It is important to have regular medical check ups, because while irregular bleeding is a common side effect of Implanon, it may rarely be caused by other medical conditions.

Ovarian cysts

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

Ectopic pregnancy

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

Implanon and pregnancy

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

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

Implanon and breastfeeding

Implanon may be used while you are breastfeeding. Implanon does not influence the production or the quality of breast milk. However, a small amount of the active substance of Implanon passes into the breast milk and may be ingested by the child.

The health of breast-fed children whose mothers were using Implanon has been studied in children up to three years of age. No effects on the growth and development of the children were observed.

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

Taking other medicines

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

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

- * medicines for epilepsy (such as primidone, phenytoin, barbiturates, carbamazepine, oxycarbamazepine, topiramate, felbamate)
- * medicines for tuberculosis (e.g. rifampicin and rifabutin)
- * medicines for HIV infections (e.g. Ritonavir, nelfinavir)
- * medicines to treat fungal infections (e.g. griseofulvin)

- * herbal medicines containing St. John's Wort primarily for the treatment of depressive moods

Your doctor or family planning counsellor can tell you if you need to take extra contraception precautions (such as a condom or cap plus spermicide) and if so for how long. They may also advise you to have Implanon removed. You should also tell any other doctor or dentist who prescribes another medicine that you are using Implanon.

When should you contact your doctor?

Regular check ups

When you are using Implanon, your doctor will tell you to return for regular check-ups. The frequency and nature of these check-ups will depend on your personal situation but should occur at least every year.

Consult your doctor as soon as possible if:

- * you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also 'When you must not use it' and 'Before you start with Implanon'); do not forget about the items related to your immediate family
- * you have severe pain or swelling in either of your legs, breathlessness, an unusual cough, especially if you cough up blood. These may be signs of thrombosis (blood clots)
- * you have a sudden, severe stomach-ache or yellowing of the skin (indicating possible liver problems)
- * you feel a lump in your breast
- * you feel sudden or severe pain in the lower abdomen or stomach area. This could indicate ectopic pregnancy or an ovarian cyst (see 'Ovarian cysts' and 'Ectopic pregnancy').

- * you have unusual, heavy vaginal bleeding.
- * you are to be immobilised or are to have surgery; tell your doctor at least 4 weeks in advance
- * you suspect that you are pregnant

How should Implanon be used?

How should Implanon be inserted and removed?

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

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

The doctor will decide in consultation with you the most suitable time for insertion. This depends on your personal situation (e.g. on the birth control method that you are currently using). Unless you are switching from another hormonal contraceptive method, insertion should be done on day 1-5 of your normal menstrual cycle to rule out pregnancy. In case of doubt please talk to your doctor.

Implanon is placed directly under the skin inside the upper non-dominant arm (the arm that you do not write with). The insertion of Implanon is not generally painful if performed with a local anaesthetic and only takes the time required for an injection.

At the end of the insertion procedure, make sure your doctor shows you how to gently feel the implant in your arm.

If you cannot feel the implant in your arm after insertion you should tell your doctor and use a condom until the presence of the rod is confirmed. In rare cases the doctor may have to use ultrasound or magnetic resonance

imaging, or may have to take a blood sample, to make sure that the implant is inside your arm.

If you would like to have Implanon replaced, a new implant can be inserted immediately after the old implant is removed. The new implant can be inserted in the same arm, often at the same site as the previous implant. Your doctor will advise you.

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

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

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

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

When to Insert Implanon

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

No preceding hormonal contraceptive use

Implanon should be inserted on day 1-5 of your natural cycle (day 1 being the first day of menstrual bleeding).

Changing from a combined oral contraceptive (COC)

Implanon should be inserted preferably on the next day following the last active tablet of the COC. At the latest it should be inserted on the day following the usual active tablet-free interval or last sugar tablet of the COC.

Changing from a progestagen-only method (minipill, or Injectable)

Implanon may be inserted on any day when switching from a minipill or from an injectable when the next injection would be due

Following Miscarriage or abortion

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

If you want to stop using Implanon

You can stop using Implanon at any time. Ask a doctor who is familiar with the technique to remove it.

If your implant is not easy to feel under the skin, removal should be performed by someone who is skilled in removal of deeply inserted Implanon.

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

If you want to have a baby, it is helpful to wait until you have had one period after Implanon has been removed before you try to get pregnant. It will be easier to work out when the baby is due.

While you are using Implanon

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

Consult your doctor promptly if any of the following happen:

If you have any of the signs of a

blood clot, as below:

- * Sudden severe pain in the chest, whether it reaches to the arm or not.
- * If you suddenly become breathless.
- * If you suddenly lose vision, partially or completely, or if you see double.
- * If you have an unusual, severe or prolonged headache.
- * If your speech is abnormal.
- * If you experience dizziness.
- * If you have a fainting attack or you collapse.
- * If one side or part of your body suddenly becomes very weak or numb.
- * If you suffer severe pain in one of your calves.

Side Effects of Implanon

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

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

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

Serious side effects

Serious reactions associated with the use of Implanon, as well as related symptoms, are described in the following sections: 'What do you need to know before and during the use of Implanon', 'Hormonal contraceptives and Thrombosis/

Hormonal contraceptives and Breast cancer'.

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

Other possible side effects

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

You should see your doctor immediately if you experience symptoms of angioedema such as:

1. swollen face, tongue or throat
2. difficulty to swallow or
3. hives and difficulties to breath.

Insertion and removal related effects

During the insertion or removal of Implanon, some bruising, pain or itching and in rare cases infection may occur. Occasionally, fibrous tissue may appear at the implantation site, or a scar or abscess will be formed. Rarely, numb feeling or sensation of numbness (or lack of feeling) may occur. Expulsion or migration of Implanon is possible, especially if the implant has not been inserted properly. Minor surgical intervention might be necessary when removing Implanon.

Tell your doctor or family planning counsellor if any side effect becomes troublesome or continues. It is also

important to tell them if you experience any other unusual or unexpected symptoms during the use of Implanon.

After Using Implanon

Storage

Store Implanon in a safe dry place below 30 degrees C and do not freeze.

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

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

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

Do not open the sterile plastic box containing the applicator.

Disposal

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

Product Description

What it looks like

Implanon is a single, small non-biodegradable semi-rigid rod, 4 cm in length and 2 mm in diameter. The rod is provided in a sterile, preloaded applicator. Do not be alarmed by the size of the box or the applicator.

Ingredients

Implanon is made of ethylene vinylacetate copolymer (a type of plastic). It contains 68 mg of etonogestrel (active ingredient).

Supplier

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