



Products and licensing

Norplant®

Although approved by the FDA in 1990, Norplant is not currently available in the United States. This contraceptive implant was confirmed to be effective for seven years by the World Health Organization.

Six thin, flexible capsules made of a soft, rubberlike material and filled with levonorgestrel are inserted just under the skin in a minor surgical procedure. Norplant has been approved for distribution in more than 50 countries.

Norplant is licensed to Bayer Schering Pharma Oy outside of the United States.

The questions and answers below are intended to provide general information about Norplant and should not serve as a substitute for a physician's advice.

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General information

What are Norplant implants? Norplant is an effective, long-acting, reversible contraceptive for women that protects for up to five years. Six thin, flexible capsules made of a soft, rubberlike material, filled with a synthetic progestin, are inserted just under the skin of a woman's upper arm in a minor surgical procedure. The implants do not contain estrogen. Protection is generally provided within 24 hours after the insertion, and the woman rapidly returns to her normal fertility when the implants are removed. The most common side effect is change in menstrual bleeding patterns.

How do Norplant implants work? Pregnancy is prevented in Norplant users by a combination of mechanisms. The most important of these are the inhibition of ovulation and the thickening of the cervical mucus, which makes it impermeable to sperm. Other mechanisms may add to these contraceptive effects.

What are the capsules' components? Norplant implants are made with silicone rubber tubing filled with a synthetic hormone. This contraceptive is not made of new ingredients; the tubing has been used in surgical applications since the 1950s and the hormone released by the implants, levonorgestrel, has been used in combined oral contraceptives and in the minipill for more than 20 years. What is different about the Norplant implant method is the way it delivers the contraceptive drug to the body.

Each of the six Norplant capsules is 34 mm (1 3/16 of an inch) long and 2.4 mm in diameter (about the size of a pocket match) and contains 36 mg of levonorgestrel, which is released at a low, steady rate.

How effective are Norplant implants? The Norplant implant method is one of the most effective reversible contraceptives available. For every 1,000 women who use Norplant implants for a year, fewer than two will become pregnant. During the first five years of use, Norplant implants have a lower failure rate than the pill or most IUDs and the method's efficacy can be compared to surgical

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sterilization. The cumulative pregnancy rate for the entire five years is 1.1 per 100 users.

The Population Council data are based on capsules made from two kinds of tubing, one denser than the other. The softer tubing, which is now commonly used, is more effective over a five-year span, because of a higher release rate of levonorgestrel into the bloodstream. Recently published data show that the softer tubing has a cumulative five-year failure rate of less than 2.0 percent.

How long are Norplant implants effective? Norplant implants have been approved for contraceptive protection for five years. All six capsules have to be inserted during the same procedure, even if the method is to be used for fewer than five years. At the end of the fifth year, when the implants should be removed, a new set may be inserted for continued protection.

Who can use Norplant implants? Norplant implants may be used by almost any woman in her fertile years who wants to avoid pregnancy. It is suitable for women who are seeking continuous, yet reversible, contraception; who want to space their children; who cannot use methods that contain estrogen; who do not want to be sterilized; and/or who desire a method that is convenient and not related to sexual intercourse. There have been no differences in reactions to Norplant implants based on a woman's race, age, or ethnic group.

Who should not use Norplant implants? Norplant implants should not be used by women who have: active thromboembolic disorders, such as blood clots in the legs, lungs, or eyes; undiagnosed genital bleeding; acute liver disease; known or suspected carcinoma of the breast; and a history of idiopathic intracranial hypertension (IIH). Also, women who are pregnant should not use Norplant implants. Women who have had previous blood clots or other thromboembolic disorders should consult with their healthcare providers on whether to use the method.

Can heavier women use them? Yes. Although pregnancy rates are higher in heavier women (over 154 lbs.), even in this group they are below those of oral contraceptives.

Does the age of the user matter? If there are no contraindications, Norplant implants may be used by women throughout their reproductive years. A young woman can start using the method once her periods become regular, which is usually about two years after the onset of her menses. Older women can use Norplant implants as they approach menopause.

What do women like most about Norplant implants? Discussions with women using Norplant implants in various countries show they liked the method's convenience, effectiveness, and reversibility. Other advantages mentioned were the method's long-term duration, limited side effects compared to other methods, and the fact that it was placed in the arm. In some societies, women are reluctant to undergo internal examinations.

What do women like least about Norplant implants? Menstrual irregularities, a side effect of Norplant that can be troublesome for many women, were cited as the least liked aspect of the method. Prior to insertions and removals, many women were concerned that the procedures might be painful. Some women also were concerned because they could not insert or remove the method themselves. With a provider-dependent method such as Norplant implants, it is important that women be able to request and receive removal on demand from providers instructed in the procedures.

How many users continue past the first year? Continuation rates have been high in clinical studies and field trials of Norplant use. Published data for the United States show a continuation rate of 88 percent in the first year. Cumulative continuation rates in seven preintroduction studies averaged 80 percent or more in succeeding years.

Why do women discontinue using this method? The principal reasons women discontinue using Norplant include: medical reasons and side effects; in order to become pregnant; or for other personal reasons. Studies conducted by the Population Council indicate that the most common side effects causing women to halt implant use in a five-year period are: menstrual irregularities (17.4 percent); headache (1.9 percent); weight changes (1.7 percent); mood changes (1.1 percent); and depression (0.9 percent).

Why is counseling important? It is important for a woman to know all about Norplant implants and how the method compares with other available contraceptives. Studies have shown that users who receive good counseling are more satisfied with the method they adopt and are more likely to continue using it. Before deciding to use Norplant implants, a woman should understand how the method works, what side effects to expect, and when to have the implants removed. She should know that insertions and removals are simple procedures when performed by trained healthcare providers, and are not painful to most women.

Insertion and removal

Should a woman considering Norplant get a physical exam first? It is recommended that a woman considering Norplant implants undergo a medical examination. This may include giving a medical history and having a pelvic exam to ensure that she has no diseases or conditions that would make it unsafe for her to use Norplant implants.

Can Norplant implants be inserted at any time? To make sure the woman is not pregnant,

Norplant implants should be inserted within seven days after the onset of menstrual bleeding, or immediately postabortion. However, Norplant implants may be inserted at any time during the menstrual cycle, provided the woman is not pregnant and effectively uses a nonhormonal method for at least seven days after insertion.

How are the capsules inserted? The implants are inserted under the skin of the inner side of the upper arm in a minor surgical procedure. A local anesthetic is injected and the clinician makes a small incision—2 mm long. The capsules are placed one at a time in a fan shape using a special hollow needle called a trocar. The procedure typically takes 10 to 15 minutes. Because a local anesthetic is used, there should be little or no pain. Usually the incision is covered with protective gauze and a small adhesive bandage.

Who performs the insertions? Generally, any specially trained physician, nurse, nurse-midwife, or other healthcare professional can do the insertion. The prevailing laws will determine who is allowed to perform the procedures. Women should confirm that their healthcare provider has been instructed in the procedure before he or she inserts or removes the Norplant implants.

Will the insertion site hurt? The needle providing the anesthetic may sting briefly. When the anesthetic wears off, there may be some tenderness for a day or two, as well as some discoloration, bruising, and/or swelling in the area for a few days after placement. There have also been reports of tingling and numbness in the arm after the procedure.

How should the insertion site be cared for? The insertion site should not be bumped for a few days and the area should be kept dry. The protective gauze bandage should be left in place for three days and the small adhesive bandage should be left on for a day or two longer.

Are Norplant implants visible? Since the incision is tiny, Norplant implants do not leave a noticeable scar on most women. The implants are comfortable and barely visible. When they are visible, the outline of the implants, resembling colorless veins, may be seen under the skin.

Will the implants move around? After Norplant capsules are inserted, they sometimes move from the original position. Infrequently, movement of a few inches has been reported. Some Norplant users have reported movement accompanied by pain or discomfort. The woman should contact her healthcare provider if this occurs.

Can a woman work after the insertion? Yes. She can resume her normal work and domestic activities, as long as she does not bump the site or get the incision site wet for at least three days.

How soon after insertion can the couple have sexual relations? Norplant becomes effective within 24 hours after insertion. If the woman has the implants inserted within seven days of her menses, she can have sexual relations without a backup method 24 hours later. If the capsules were inserted at another time of the menstrual cycle, the woman should use a nonhormonal backup method.

When should a woman return to the clinic after she receives Norplant implants? The follow-up schedule depends on the practice of the particular clinic or physician's office in which a woman receives the implants. She may be asked to return for periodic health checkups or to report on her experience with the implants. She should be encouraged to return to the same provider or clinic if she has any health problems that worry her; if she wants a child; or if she is moving away and needs the address of a clinic in her new area that provides Norplant services.

Annual checkups, besides being good medical practice, offer an occasion to remind women to have their implants removed at five years.

How is Norplant implant protection reversed? One of the most important characteristics of Norplant implants is their reversibility. The contraceptive action stops within two to three days after the implants are removed during a clinical procedure, under a local anesthetic, similar to the insertion process.

When should Norplant implants be removed? Norplant implants must be removed at the end of five years when they become less effective. Before that time, however, the woman should be able to request and obtain removal of the implants at any time, for either a personal or medical reason.

What happens if the implants are not removed after five years? More than two-thirds of the hormone remains in the capsules after five years of use. After that time, the implants will gradually become less effective. While the implants should be removed at five years, there is no cause for panic if removal is delayed for a few months.

Who should remove the implants? The implants can be removed at the same clinic or office where they were inserted or at another health facility that offers Norplant implants. As with insertion, a woman should confirm that her clinician has been instructed in the removal procedure prior to removing the implants.

Is removal painful? Just as when the capsules were inserted, the health professional will apply a local anesthetic so the woman should not feel pain. It is not necessary to use general anesthesia for

this procedure. Clinicians should feel the site to be sure they can locate all six capsules prior to removing them. If they cannot be felt, the implants can be located through x-ray or ultrasound, which are painless procedures.

A small incision—not longer than 4 mm—will be made, through which all the implants are removed. When the anesthetic wears off, there may be some tenderness, discoloration, bruising, and swelling in the area for a few days.

Are removals more difficult than insertions? How long does removal take? Although most removals are not difficult, the removal procedure usually takes longer than insertion. Some implants may be harder than others to locate and remove if they were inserted too deeply or if temporary swelling of the arm occurs during removal. There have been reports of nerve injury, most commonly associated with deep placement and removal. If the clinician is unable to remove all the capsules at one time, the woman should return at another time after her arm heals. Women should be informed of the possibility of needing a subsequent visit for removal and should not be alarmed if this is necessary.

How should women care for the site after removal? As with insertion, it is important to avoid rough contact with the removal site for a few days. The area should be kept clean, dry, and bandaged until healed (3 to 5 days) so that the site does not become infected.

How soon afterward can a woman become pregnant? The reversibility of Norplant implants is one of the important advantages of the method. Once the implants are removed, the contraceptive effect wears off quickly (within two to three days). The woman can become pregnant as rapidly as she would have if she had used another reversible method or if she had used no method during the time Norplant was inserted in her arm.

Can another set of implants be inserted when the old set is removed? Yes. If a woman wants to continue using Norplant, a new set of implants can be inserted when the old set is removed. The second set can be placed through the incision from which the earlier set was removed, in the same or opposite direction, or in the other arm. If a woman does not want to continue with Norplant implants and does not want to become pregnant, she should be offered another contraceptive method before she leaves the clinic.

Side effects and health considerations

What are the side effects of Norplant? The most common side effect of Norplant use is irregular menstrual bleeding. Irregularities vary from woman to woman and may include: prolonged menstrual bleeding during the first months of use (rarely heavy bleeding); untimely bleeding or spotting between periods; no bleeding at all for several months and, in some cases, for a year or longer; or a combination of these patterns.

Other side effects experienced with Norplant are frequently associated with use of hormonal methods. Side effects reported by users that are probably related to Norplant implants include: headache (the most frequent complaint after menstrual irregularities); dizziness; nervousness; anxiety; nausea, and vomiting; adnexal enlargement; itching/rashes; acne; change of appetite; weight gain; breast tenderness; excessive hair growth; hair loss; and discoloration of the skin at the insertion site.

Preexisting conditions of acne or excessive growth of body or facial hair could worsen. Occasionally, an infection may occur at the implant site (which can be treated with an antibiotic), or there may be a brief incidence of pain, itching, numbness, or tingling in the arm of insertion.

How frequently do Norplant side effects occur? Bleeding irregularities (including spotting, longer or heavier periods, or no bleeding) are reported by 70 to 80 percent of Norplant users. Both increased and reduced bleeding tend to diminish with time.

Percentages of users reporting the other more common side effects during the first year of use are: headache (18 percent); skin problems including dermatitis and acne (15 percent); and nausea (8 percent). Appetite changes, weight changes, and nervousness are each reported by 6 percent of users.

Are the bleeding irregularities associated with Norplant implants serious? Most bleeding irregularities associated with Norplant® use are not serious, although they may be troublesome for some users. Change in the menstrual bleeding pattern—the most frequently reported side effect—is to be expected with hormonal methods that do not contain estrogen. If a woman experiences heavy bleeding, she should make a follow-up visit to her physician or healthcare provider.

What kind of bleeding pattern can be expected? It is not possible to predict the kind of bleeding pattern a woman will have while using Norplant implants. There is some evidence of a correlation between a woman's weight and the kind of bleeding irregularities she will have. Some studies indicate that very thin women are more likely to be amenorrheic, while heavier women have more bleeding and spotting days, but accurate predictions of how she will react to the method cannot be made. Both increased and reduced bleeding tend to diminish with time. Many women can expect an altered menstrual bleeding pattern to become more regular after six to nine months.

Is the lack of bleeding harmful? Sometimes a woman is concerned about amenorrhea—no monthly bleeding at all. A woman's health or future fertility will not be harmed if she does not have her period while using Norplant; there is no blood "buildup." If a woman wants to make sure she is not pregnant, she can return to the clinic for a pregnancy test. She is probably not pregnant, but the test might reassure her.

Does the use of Norplant implants make women anemic? Despite the increased frequency of menstrual bleeding in some women using Norplant, the amount of total blood loss is usually less than normal menses. In some studies, in fact, hemoglobin values of Norplant implant users have been shown to increase. There have been a few rare exceptions of severe blood loss.

Should women be given estrogen to control bleeding and spotting? Norplant implants are estrogen-free and many women and their healthcare providers choose the method for exactly this reason. Research is being conducted to test the effectiveness of a few treatments for bleeding irregularities, but it is still too early to tell whether any will be successful. As of now, the best way to handle irregular bleeding is through sensitive and thorough counseling of women who want the method. Research has shown that women who have been well counseled about what to expect with implants are more likely to find the method acceptable and to continue with it.

How do Norplant implants affect the body's chemistry? Extensive clinical pharmacology research has shown no adverse effects of progestin implant use on endocrine patterns, the endometrium, lipoproteins, adrenal function, thyroid function, and a variety of other physiological indicators in healthy women. These studies also have given no indication of cardiovascular, respiratory, central nervous system, or other serious problems, nor is there any evidence of carcinogenicity or teratogenicity associated with Norplant implant use in healthy women.

Certain conditions present before implant use, such as diabetes, may be affected by Norplant use; women with these conditions should be carefully monitored. (See additional questions in this section for specific conditions.)

What are warning signs of possible problems? A woman using Norplant implants should return to her healthcare provider or clinic right away if she has: severe lower abdominal pain (possible ectopic pregnancy); heavy vaginal bleeding; arm pain; pus or bleeding at the insertion site (an indication of infection); expulsion of an implant (this rarely occurs with proper placement); episodes of migraine or repeated severe headaches; blurred vision; or delayed menstrual cycles after a long interval of regular cycles.

Failure to have periods after regular cycles may be a sign of pregnancy. If the woman is not bleeding at her expected time and has lower abdominal pain or symptoms of pregnancy, she should visit the clinic without delay.

Are there other health considerations with Norplant use? Women with certain health conditions can use Norplant implants, provided they have regular checkups. If a woman has any of the following conditions, she should discuss them with her healthcare provider before using the method: breast nodules, fibro-cystic disease of the breast, an abnormal breast x-ray or mammogram; diabetes; elevated cholesterol or triglycerides; high blood pressure; migraine or other headaches; epilepsy; mental depression; gallbladder, heart, or kidney disease; a history of blood clots, heart attack, or stroke; or a history of scanty or irregular menses.

Does Norplant cause heart or vascular problems? Although there have been postmarketing reports of stroke, myocardial infarction, and certain vascular problems such as thromboembolic disorders (all of which occur among the general population) among Norplant users; no cause-and-effect relationship between Norplant use and these conditions has been shown.

Thrombophlebitis and superficial phlebitis have also been reported among Norplant users, most commonly occurring in the arm of insertion. (See below for more information on stroke and heart attacks among smokers.)

Does Norplant cause autoimmune diseases? Autoimmune diseases such as scleroderma, systemic lupus, and rheumatoid arthritis occur in the general population and more frequently among women of childbearing age. There have been rare reports of various autoimmune diseases, including those listed above, in Norplant users; however, the rate is significantly less than the rate among the general population of women of reproductive age. While it is believed that the occurrence of autoimmune diseases among Norplant users is coincidental, healthcare providers should be alert to the earliest manifestations of these diseases.

Does Norplant cause birth defects? Although there have been rare reports of birth defects in offspring of women who were using Norplant inadvertently during early pregnancy, these conditions are not believed to be caused by Norplant use. However, if a woman becomes pregnant while using the implants, they must be removed immediately.

Can a smoker use Norplant implants? Cigarette smoking increases the risk of heart attacks and strokes in users of combined (estrogen-progestin) oral contraceptives. This risk increases with age and with heavy smoking (15 or more cigarettes a day) and is quite marked in women over 35 years old. While this is believed to be an estrogen-related effect, it is not known whether a similar risk exists with progestin-only methods such as Norplant implants. Therefore, a woman who

chooses to use Norplant implants is advised not to smoke.

Do Norplant implants protect against sexually transmitted infections? No. This form of contraception does not protect against sexually transmitted infections (STIs). If a woman thinks she might be at risk for STIs, she and her partner should use a condom in addition to the implants.

Can a woman use Norplant implants if she is breastfeeding? Hormonal methods are not considered the most appropriate contraceptives for breastfeeding women. However, studies have shown no significant effects on the growth or health of infants whose mothers used levonorgestrel implants beginning six weeks after childbirth. There is no experience to support the use of Norplant implants earlier than six weeks after childbirth.

Is sickle cell anemia a contraindication? Sickle cell anemia is not considered a contraindication for the use of Norplant implants. However, the Council does not have data from clinical trials, since women who were anemic were not included in the Council's studies with Norplant implants.

Do other drugs interact with Norplant implants? Certain drugs may interact with the hormone delivered by Norplant implants to make them less effective in preventing pregnancy. These include drugs used for epilepsy such as phenytoin (like Dilantin), and drugs for rheumatoid conditions such as phenylbutazone (Butazolidin is one brand). A woman using Norplant implants should tell her healthcare provider if she is taking any of these medications.

Is there a risk of ectopic pregnancy? The risk of ectopic pregnancy (a fetus developing outside the uterus) is very low, because of the high effectiveness of the method. Ectopic pregnancies have occurred among women using Norplant implants at an average rate of 1.3 per 1,000 woman-years, less than the overall ectopic rate of women in the United States during the 1980s. The risk may increase with the duration of Norplant implant use or with increased weight of the user. It is important, therefore, that the implants be removed at the end of five years when they become less effective.

Are ovarian cysts a problem for the users of Norplant implants? Functional ovarian cysts or enlarged follicles sometimes occur in Norplant users, as they do in women who do not use Norplant implants. These enlarged follicles may produce discomfort in some women, although most users would not be aware of them unless they were found during a physical exam. In the majority of women, enlarged follicles will disappear on their own and should not require surgery. Rarely, they may twist or rupture so that surgery is required.

Are long-term side effects known? Long-term side effects of Norplant use are not yet known. However, the drug contained in Norplant, levonorgestrel, has been used in oral contraceptives for over 20 years.

To learn more about any possible rare, medium-term health effects related to the method, the World Health Organization, the Population Council, and Family Health International are conducting an international postmarketing surveillance of Norplant implant use. Some 8,000 method users and discontinuers, and an equal number of controls, in eight developing countries have been followed for five years.

Research and development

Why were Norplant implants developed? The Population Council developed Norplant implants to expand contraceptive options for women, by offering a method that was convenient, long-acting, and reversible. In addition, the implants deliver a very low dose of progestin and contain no estrogen.

Why are additional contraceptives needed? There is currently no reversible contraceptive that all women like and are able to use. A woman may try several methods until she finds the one that best suits her. Furthermore, a woman may switch methods several times during her reproductive lifetime because of changes in her age, health, economic security, marital status, lifestyle, and concept of ideal family size. All of these factors can have an impact on her decisions about contraception: when to use or stop using it, what kind to use, and when to switch to another method.

Even with Norplant implants as an option, there is a need for new contraceptives for groups of women whose needs are not met by existing methods.

Where were Norplant implants tested? Norplant implants were tested in four developing and four developed countries, including the United States. In addition, many countries have conducted preintroduction studies to obtain data on local experience with the method and to train providers in insertion, removal, and counseling techniques. By 1991, when the method became available in the United States, Norplant implants had been studied in clinical trials and preintroduction studies involving over 55,000 volunteers in more than 40 countries.

Where have Norplant implants been approved? By July 1995, the method was approved in 44 countries, including Sweden, France, the United Kingdom, and the United States. The US Food and Drug Administration approved Norplant for marketing in December 1990.

Is there a risk of Norplant being used coercively? Yes. There is a risk of any provider-controlled method being used coercively. The Population Council advocates solely the voluntary use of any contraceptive. Women have the right to balanced and accurate information, trained and capable healthcare providers, aseptic conditions, and the ability to discontinue the method whenever they choose to do so. When a method is provider-dependent, informed consent should always be obtained at the time the method is adopted, and Norplant users should have ready access to removal of the implants by capable health care providers.

The Council has worked since 1983 to encourage introduction of implants with concern for user satisfaction and emphasis on the quality of care in the provision of family planning services.

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