

**DEPO-PROVERA®
Contraceptive Injection
medroxyprogesterone acetate injectable suspension, USP**

Patient Labeling

Use of Depo-Provera Contraceptive Injection may cause you to lose calcium stored in your bones. The longer you use Depo-Provera Contraceptive Injection the more calcium you are likely to lose. The calcium may not return completely once you stop using Depo-Provera Contraceptive Injection.

Loss of calcium may cause weak, porous bones (osteoporosis) that could increase the risk that your bones might break, especially after menopause. It is not known whether your risk of developing osteoporosis may be greater if you are a teenager when you start to use Depo-Provera Contraceptive Injection.

You should use Depo-Provera Contraceptive Injection long term (for example, more than two years) only if other methods of birth control are not right for you. (See “Risks of Using Depo-Provera Contraceptive Injection”)

This product is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Introduction

Every woman who considers using DEPO-PROVERA Contraceptive Injection needs to understand the benefits and risks of this form of birth control and to discuss them with her health-care provider. This leaflet is intended to give you much of the information you will need in order to decide if DEPO-PROVERA Contraceptive Injection is the right choice for you. Your health-care provider will help you to compare DEPO-PROVERA Contraceptive Injection with other contraceptive methods and will answer any questions you have after you have read this information.

DEPO-PROVERA Contraceptive Injection is given as an intramuscular injection (a shot) in the buttock or upper arm once every 3 months (13 weeks). Promptly at the end of the 3-month interval, you will need to return to your health-care provider for your next injection in order to continue your contraceptive protection.

DEPO-PROVERA Contraceptive Injection contains medroxyprogesterone acetate, a chemical similar to (but not the same as) the natural hormone progesterone that is produced by your ovaries during the second half of your menstrual cycle. DEPO-PROVERA Contraceptive Injection acts by preventing your egg cells from ripening. If an egg is not released from the ovaries during your menstrual cycle, it cannot become fertilized by sperm and result in pregnancy. DEPO-PROVERA Contraceptive Injection also causes changes in the lining of your uterus that make it less likely for pregnancy to occur.

Effectiveness of DEPO-PROVERA Contraceptive Injection

To ensure that DEPO-PROVERA Contraceptive Injection is not administered inadvertently to a pregnant woman, the first injection must be given **ONLY** during the first 5 days of a normal menstrual period; **ONLY** within the first 5-days postpartum if not breast-feeding, and if exclusively breast-feeding, **ONLY** at the sixth postpartum week (see **Administration of DEPO-PROVERA Contraceptive Injection**). The efficacy of DEPO-PROVERA Contraceptive Injection depends on adherence to the recommended dosage schedule.

DEPO-PROVERA Contraceptive Injection is over 99% effective, making it one of the most reliable methods of birth control available. This means that the average annual pregnancy rate is less than one for every 100 women who use DEPO-PROVERA Contraceptive Injection. The effectiveness of most contraceptive methods depends, in part, on how reliably each woman uses the method. The effectiveness of DEPO-PROVERA Contraceptive Injection depends only on the patient returning every 3 months (13 weeks) for her next injection.

The following table shows the percent of women who become pregnant while using different kinds of contraceptive methods. It gives both the lowest expected rate of pregnancy (the rate expected in women who use each method exactly as it should be used) and the typical rate of pregnancy (which includes women who became pregnant because they forgot to use their birth control or because they did not follow the directions exactly).

Percent of Women Experiencing an Accidental Pregnancy in the First Year of Continuous Use

Method	Lowest	Typical
DEPO-PROVERA	0.3	0.3
Implants (Norplant)	0.2*	0.2*
Female sterilization	0.2	0.4
Male sterilization	0.1	0.15
Oral contraceptives (pill)	—	3
Combined	0.1	—
Progestogen only	0.5	—
IUD	—	3
Progestasert	2	—
Copper T 380A	0.8	—
Condom (without spermicide)	2	12
Diaphragm (with spermicide)	6	18
Cervical cap	6	18
Withdrawal	4	18
Periodic abstinence	1–9	20
Spermicide alone	3	21
Vaginal sponge	—	—
used before childbirth	6	18
used after childbirth	9	28
No method	85	85

Source: Trussell et al; *Obstet Gynecol* 1990;76:558–567.

* From Norplant[®] package insert.

Who Should Not Use DEPO-PROVERA Contraceptive Injection

Certain women should not use DEPO-PROVERA Contraceptive Injection. You should not use DEPO-PROVERA Contraceptive Injection if you have any of the following conditions:

- if you think you might be pregnant
- if you have any vaginal bleeding without a known reason
- if you have had cancer of the breast
- if you have had a stroke
- if you have or have had blood clots (phlebitis) in your legs
- if you have problems with your liver or liver disease
- if you are allergic to DEPO-PROVERA Contraceptive Injection (medroxyprogesterone acetate or any of its other ingredients)

Other Things to Consider Before Choosing DEPO-PROVERA Contraceptive Injection

Before your doctor prescribes DEPO-PROVERA Contraceptive Injection, you will have a physical examination. It is important to tell your doctor or health-care provider if you have any of the following:

- a family history of cancer of the breast
- an abnormal mammogram (breast X-ray), fibrocystic breast disease, breast nodules or lumps, or bleeding from your nipples
- kidney disease
- irregular or scanty menstrual periods
- high blood pressure
- migraine headaches
- asthma
- epilepsy (convulsions or seizures)
- diabetes or a family history of diabetes
- a history of depression
- if you are taking any prescription or over-the-counter medications

This product is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

Return of Fertility

Because DEPO-PROVERA Contraceptive Injection is a long-acting birth control method, it takes some time after your last injection for its effect to wear off. Based on the results from a large study done in the United States, of those women who stop using DEPO-PROVERA Contraceptive Injection in order to become pregnant, about half of those who become pregnant do so in about 10 months after their last injection; about two-thirds of those who become pregnant do so in about 12 months, about 83% of those who become pregnant do so in about 15 months, and about 93% of those who become pregnant do so in about 18 months after their last injection. The length of time you use DEPO-PROVERA Contraceptive Injection has no effect on how long it takes you to

become pregnant after you stop using it.

Risks of Using DEPO-PROVERA Contraceptive Injection

1. Losing Calcium from Your Bones

Depo-Provera CI use may decrease the amount of calcium in your bones. The longer you are on Depo-Provera CI the more calcium you may lose. This increases the risk of your bones weakening if you use Depo-Provera CI continuously for a long time (for more than 2 years). The loss of calcium may increase your risk of osteoporosis and broken bones, particularly after your menopause.

Calcium is generally added to the bones during teenage years. The decrease of calcium in your bones is of most concern if you are a teenager or have the following risk factors:

- bone disease
- anorexia nervosa (an eating disorder)
- a strong family history of osteoporosis
- drug use that can lower the amount of calcium in bones (drugs for epilepsy or steroids), or
- drinking a lot of alcohol or smoking a lot.

If you need a birth control method for more than 2 years, your healthcare provider may ask you to switch to another birth control method or ask you to have a test of your bones before continuing Depo-Provera CI, especially if you have other risks for weak bones. When Depo-Provera CI is stopped, the calcium in bones begins to come back. Your healthcare provider may tell you take calcium and Vitamin D as this may lessen the loss of calcium from your bones.

2. Irregular Menstrual Bleeding

The side effect reported most frequently by women who use DEPO-PROVERA Contraceptive Injection for contraception is a change in their normal menstrual cycle. During the first year of using DEPO-PROVERA Contraceptive Injection, you might have one or more of the following changes:

- irregular or unpredictable bleeding or spotting,
- an increase or decrease in menstrual bleeding, or
- no bleeding at all.

Unusually heavy or continuous bleeding, however, is not a usual effect of DEPO-PROVERA Contraceptive Injection and if this happens you should see your health-care provider right away.

With continued use of DEPO-PROVERA Contraceptive Injection, bleeding usually decreases and many women stop having periods completely. In clinical studies of DEPO-PROVERA Contraceptive Injection, 55% of the women studied reported no menstrual bleeding (amenorrhea) after 1 year of use and 68% of the women studied reported no menstrual bleeding after 2 years of use.

The reason that your periods stop is because DEPO-PROVERA Contraceptive Injection causes a resting state in your ovaries. When your ovaries do not release an egg monthly, the regular monthly growth of the lining of your uterus does not occur and, therefore, the bleeding that comes with your normal menstruation does not take place. When you stop using DEPO-PROVERA Contraceptive Injection your menstrual period

will usually, in time, return to its normal cycle.

3. Cancer

Studies of women who have used different forms of contraception found that women who used DEPO-PROVERA Contraceptive Injection for contraception had no increased overall risk of developing cancer of the breast, ovary, uterus, cervix, or liver. However, women under 35 years of age whose first exposure to DEPO-PROVERA Contraceptive Injection was within the previous 4 to 5 years may have a slightly increased risk of developing breast cancer similar to that seen with oral contraceptives. You should discuss this with your health-care provider.

4. Unexpected Pregnancy

Because DEPO-PROVERA Contraceptive Injection is such an effective contraceptive method, the risk of unexpected pregnancy for women who get their shots regularly (every 3 months [13 weeks]) is very low. While there have been reports of an increased risk of low birth weight and neonatal infant death or other health problems in infants conceived close to the time of injection, such pregnancies are uncommon. If you think you may have become pregnant while using DEPO-PROVERA Contraceptive Injection for contraception, see your health-care provider as soon as possible.

5. Allergic Reactions

Severe allergic reactions known as anaphylaxis and anaphylactoid reactions have also been reported in some women using DEPO-PROVERA Contraceptive Injection.

6. Other Risks

Women who use hormone-based contraceptives may have an increased risk of blood clots or stroke. Also, if a contraceptive method fails, there is a possibility that the fertilized egg will begin to develop outside of the uterus (ectopic pregnancy). While these events are rare, you should tell your health-care provider if you have any of the Warning Signals listed in the next section.

Warning Signals

If any of these problems occur following an injection of DEPO-PROVERA Contraceptive Injection, call your healthcare provider immediately:

- Sharp chest pain, coughing up of blood, or sudden shortness of breath (indicating a possible clot in the lung)
- Sudden severe headache or vomiting, dizziness or fainting, problems with your eyesight or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Severe pain or swelling in the calf (indicating a possible clot in the leg)
- Unusually heavy vaginal bleeding
- Severe pain or tenderness in the lower abdominal area
- Persistent pain, pus, or bleeding at the injection site

Side Effects of DEPO-PROVERA Contraceptive Injection

1. Weight Gain

You may experience a weight gain while you are using DEPO-PROVERA Contraceptive Injection. About two-thirds of the women who used DEPO-PROVERA Contraceptive Injection in the clinical trials reported a weight gain of about 5 pounds during the first year of use. You may continue to gain weight after the first year. Women in one large study who used DEPO-PROVERA Contraceptive Injection for 2 years gained an average

total of 8.1 pounds over those 2 years, or approximately 4 pounds per year. Women who continued for 4 years gained an average total of 13.8 pounds over those 4 years, or approximately 3.5 pounds per year. Women who continued for 6 years gained an average total of 16.5 pounds over those 6 years, or approximately 2.75 pounds per year.

2. Other Side Effects

In a clinical study of over 3,900 women who used DEPO-PROVERA Contraceptive Injection for up to 7 years, some women reported the following effects that may or may not have been related to their use of DEPO-PROVERA Contraceptive Injection:

- irregular menstrual bleeding
- amenorrhea
- headache
- nervousness
- abdominal cramps
- dizziness
- weakness or fatigue
- decreased sexual desire
- leg cramps
- nausea
- vaginal discharge or irritation
- breast swelling and tenderness
- bloating
- swelling of the hands or feet
- backache
- depression
- insomnia
- acne
- pelvic pain
- no hair growth or excessive hair loss
- rash
- hot flashes
- joint pain

Other problems were reported by very few of the women in the clinical trials, but some of these could be serious. These include: convulsions, jaundice, urinary tract infections, allergic reactions, fainting, paralysis, osteoporosis, lack of return to fertility, deep vein thrombosis, pulmonary embolus, breast cancer, or cervical cancer. If these or any other problems occur during your use of DEPO-PROVERA Contraceptive Injection, discuss them with your health-care provider.

General Precautions

1. Missed Periods

During the time you are using DEPO-PROVERA Contraceptive Injection for contraception, you may skip a period, or your periods may stop completely. If you have been receiving your injection of DEPO-PROVERA Contraceptive Injection regularly every 3 months (13 weeks), then you are probably not pregnant. However, if you think that you may be pregnant, see your health-care provider.

2. Laboratory Test Interactions

If you are scheduled for any laboratory tests, tell your health-care provider that you are using DEPO-PROVERA Contraceptive Injection for contraception. Certain blood tests are affected by hormones such as DEPO-PROVERA Contraceptive Injection.

3. Drug Interactions

Cytadren (aminoglutethimide) is an anticancer drug that may significantly decrease the effectiveness of DEPO-PROVERA Contraceptive Injection if the two drugs are given during the same time.

4. Nursing Mothers

Although DEPO-PROVERA Contraceptive Injection can be passed to the nursing infant in the breast milk, no harmful effects have been found in these children. DEPO-PROVERA Contraceptive Injection does not prevent the breasts from producing milk, so it can be used by nursing mothers. However, to minimize the amount of DEPO-PROVERA Contraceptive Injection that is passed to the infant in the first weeks after birth, you should wait until 6 weeks after childbirth before you start using DEPO-PROVERA Contraceptive Injection for contraception.

Administration of DEPO-PROVERA Contraceptive Injection

The recommended dose of DEPO-PROVERA Contraceptive Injection is 150 mg every 3 months (13 weeks) given in a single intramuscular injection in the buttock or upper arm. To ensure that you are not pregnant at the time of the first injection, it is essential that the injection be given **ONLY** during the first 5 days of a normal menstrual period. If used following the delivery of a child, the first injection of DEPO-PROVERA Contraceptive Injection **MUST** be given within 5 days after childbirth if you are not breast-feeding, or if you are exclusively breast-feeding, the injection **MUST** be given 6 weeks after childbirth. If you wait longer than 3 months (13 weeks) between injections, or longer than 6 weeks after delivery, your health-care provider should determine that you are not pregnant before giving you your injection of DEPO-PROVERA Contraceptive Injection.

Rx only



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