

## Patient Information About

depo-subQ provera 104™  
 medroxyprogesterone acetate injectable suspension  
 104 mg/0.65 mL

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT depo-subQ provera 104?

**Use of depo-subQ provera 104 may cause you to lose calcium stored in your bones.** The longer you use depo-subQ provera 104 the more calcium you are likely to lose. The calcium may not return completely once you stop using depo-subQ provera 104.

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-subQ provera 104.

**You should use depo-subQ provera 104 long-term (for example, more than 2 years) only if other methods of birth control are not right for you.**

**depo-subQ provera 104 does not protect you from HIV (AIDS) and other diseases spread through sex (STDs).**

### WHAT IS depo-subQ provera 104?

depo-subQ provera 104 is a drug for birth control. It also helps relieve pain related to endometriosis (**en-do-ME-tree-OH-sis**). Symptoms of endometriosis arise when cells normally inside your uterus grow outside the uterus. The cells respond to menstrual cycle hormones, and may cause painful periods, pelvic pain, and painful sex.

depo-subQ provera 104 contains a hormone called medroxyprogesterone acetate (MPA). It is given as a shot (injection) every 3 months. Three months is the same as 12 to 14 weeks.

### HOW WELL DOES depo-subQ provera 104 WORK FOR PREVENTING PREGNANCY?

When you use depo-subQ provera 104 correctly, the chance of getting pregnant is very low. In studies, no women became pregnant during the year they used depo-subQ provera 104 injection.

The list below estimates the chances of getting pregnant using different types of birth control. The numbers are based on typical use. Typical use includes people who use the method correctly and people who use the method incorrectly. The list shows the number of women out of 100 women who will likely get pregnant if they use the method for one year.

<i>Method</i>	<i>Typical chance of getting pregnant in 1 year (No. of pregnancies in 100 women)</i>
Shot	Less than 1
Implant	
Female sterilization	
Male sterilization	
IUD (copper IUD and levonorgestrel IUD)	

(continued)

<i>Method</i>	<i>Typical chance of getting pregnant in 1 year (No. of pregnancies in 100 women)</i>
Pill	5
Condom alone (male)	14
Withdrawal	19
Diaphragm with spermicides	20
Condom alone (female)	21
Periodic abstinence	25
Spermicides alone	26
Vaginal sponge or Cervical cap with spermicide	20 to 40

### HOW WILL I GET depo-subQ provera 104?

depo-subQ provera 104 is given as a shot just under the skin on your thigh or belly. You get it once every 3 months.

### For Birth Control:

#### First Shot:

Your healthcare provider will want to be sure that you are not pregnant before you get your first shot. Normally, you get the shot by the 5<sup>th</sup> day from the START of your menstrual period. You get it whether or not you are still bleeding.

If you are breast-feeding, you may have your first shot as early as 6 weeks after you deliver your baby.

#### After the first shot:

It is very important to keep getting depo-subQ provera 104 every 3 months. If you wait more than 14 weeks between shots, you could become pregnant. Your healthcare provider must make sure you are not pregnant before you get your next shot.

**When you get your shot, make an appointment for your next shot. Mark it on your calendar.**

If you need a birth control method for more than two years, your healthcare provider may ask you to have a test of your bones or ask you to switch to another birth control method before continuing depo-subQ provera 104, especially if you have other risks for weak bones.

#### For Endometriosis:

If you have regular periods, you get depo-subQ provera 104 the same way as described above for birth control. If your periods have stopped or are not regular, your healthcare provider must test to make sure you are not pregnant before you get your first shot.

It is not recommended that you receive depo-subQ provera 104 for treatment of endometriosis for longer than two years. If your painful symptoms return after stopping treatment, your healthcare provider should ask you to have a test of your bones before restarting treatment.

#### WHAT IF I MISS A SHOT?

- If you miss a shot, or wait longer than 14 weeks between shots, you could get pregnant. The longer you wait, the greater the risk of getting pregnant.
- Talk with your healthcare provider to find out when to restart depo-subQ provera 104. You should be tested to be sure you are not pregnant.
- Use another kind of nonhormonal birth control, such as condoms, until you start depo-subQ provera 104 again.

## **DO NOT TAKE depo-subQ provera 104 IF YOU...**

- Are pregnant or might be pregnant
- Have any unexplained vaginal bleeding
- Ever had breast cancer
- Ever had serious blood clots, such as blood clots in your legs (deep venous thrombophlebitis), lungs (pulmonary embolism), heart (heart attack), or head (stroke)
- Have liver disease
- Are allergic to anything in depo-subQ provera 104. (There is a list of what is in depo-subQ provera 104 at the end of this leaflet.)

## **BEFORE TAKING depo-subQ provera 104**

Your healthcare provider may do a physical examination and check your blood and urine.

## **Tell your healthcare provider about all your medical conditions.**

Most important, tell your healthcare provider if you:

- Are pregnant or might be pregnant. You should not get depo-subQ provera 104 if you are pregnant.
- Plan to become pregnant in the next year. After you stop getting depo-subQ provera 104, it takes time for your body to be able to get pregnant. It can be as early as 1 week after the last shot wears off. Most likely it will take up to 1 year or longer for you to get pregnant.
- Have breast cancer in your family
- Have an abnormal mammogram (breast X-ray), lumps in your breast, or bleeding from your nipples
- Have irregular, light, or heavy menstrual periods
- Have or had any of the following medical problems:
  - Kidney problems
  - High blood pressure
  - Migraine headaches
  - Asthma
  - Seizures
  - Diabetes, or if it runs in your family
  - Depression
  - Heart attack, stroke, or developed blood clots
  - 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)
  - Drinking a lot of alcohol or smoking a lot

It is important to see your healthcare provider regularly if you have any of these conditions.

Tell your healthcare provider about all the medicines you take. This includes prescription and over-the-counter medicines, vitamins, and herbal products.

## **WHAT ELSE SHOULD I KNOW ABOUT TAKING depo-subQ provera 104?**

**Other Birth Control.** If you can't take birth control pills or can't use a birth control patch or ring, you may be able to use depo-subQ provera 104. Ask your healthcare provider.

**Pregnancy.** When you take depo-subQ provera 104 every 3 months, your chance of getting pregnant is very low. You could miss a period or have a light period and not be pregnant. If you miss 1 or 2 periods and think you might be pregnant, see your healthcare provider as soon as possible.

You should not use depo-subQ provera 104 if you are pregnant. However, depo-subQ provera 104 taken by accident during pregnancy does not seem to cause birth defects.

**Pregnancy in your tubes (Ectopic Pregnancy).** If you have severe pain low in your belly, tell your healthcare provider right away. Infrequently, a baby may start to grow outside the uterus, most often in the tubes.

**Nursing a baby. Wait at least 6 weeks after your baby is born to start depo-subQ provera 104. You can use depo-subQ provera 104 if you are nursing.**

- It does not lower the amount of milk you can make.
- It can pass through breast milk into your baby, but it is not harmful.

**Blood or urine tests.** depo-subQ provera 104 may affect blood or urine test results. Tell your healthcare provider you are taking depo-subQ provera 104 if you are going to have blood or urine tests.

**Other medicines.** depo-subQ provera 104 may not work as well if you are also taking Cytadren (aminoglutethimide), a cancer medicine. You may need to use another kind of birth control.

## **WHAT ARE THE MOST SERIOUS RISKS OF depo-subQ provera 104?**

- **Losing calcium from your bones.** depo-subQ provera 104 use may decrease the amount of calcium in your bones. The longer you use depo-subQ provera 104, the more calcium you are likely to lose. This increases the risk of your bones weakening if you use depo-subQ provera 104 continuously for a long time (for example, if you use depo-subQ provera 104 for more than two 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 two years, your healthcare provider may ask you to have a test of your bones or ask you to switch to another birth control method before continuing depo-subQ provera 104, especially if you have other risks for weak bones. When depo-subQ provera 104 is stopped, the calcium in your bones begins to come back. The lost calcium may not return completely once you stop using depo-subQ provera 104. Your healthcare provider may tell you to take calcium and Vitamin D as this may lessen the loss of calcium from your bones.

- **Abnormal or very heavy bleeding.** If you start having very heavy or very long periods, tell your healthcare provider.
- **Liver problems.** Your healthcare provider may stop depo-subQ provera 104 if you have liver problems. Some signs of liver problems are yellow skin or eyes, feeling like you have the flu, feeling more tired than usual, and itching. Tell your healthcare provider if you have these symptoms.
- **Allergic reaction.** Allergic reactions to depo-subQ provera 104 are not common. If you have hives, problems breathing, or just do not feel right after your shot, call your healthcare provider or go to the Emergency Room right away.

- **Serious blood clots.** Call your healthcare provider immediately if you:
  - Have sharp chest pain, cough blood, or suddenly have trouble breathing
  - Have a sudden severe headache with vomiting, blindness or trouble talking, weakness, or numbness in an arm or leg, or get dizzy or faint
  - Have swelling or severe pain in your leg

#### **WHAT ARE COMMON SIDE EFFECTS OF depo-subQ provera 104?**

The most common side effects are:

- Changes in your monthly periods. You may not know when you will bleed, your periods may not be regular, you may have heavy bleeding, or you may have spotting. You may have more days of bleeding during the first 2 or 3 months after you start depo-subQ provera 104. Over time, you may have less and less bleeding. Many women stop having periods by the end of one year. Your periods will come back eventually after you stop using depo-subQ provera 104.
- Weight gain. In studies, women gained an average of 3 to 4 pounds during the first year they used depo-subQ provera 104. After 2 years of using depo-subQ provera 104, women gained an average of 7 to 8 pounds. Some women gained more, some gained less, some lost, and some stayed the same. Weight changes beyond 2 years of use with depo-subQ provera 104 have not been studied. Women who used a similar birth control product for 5 years gained on average 5 pounds more than women who did not use a hormone contraceptive product.
- Skin reaction where you got the shot. Lumps, skin dimpling, or pain are usually mild and usually don't last long. Scarring is unusual, but may happen. If there is swelling or your skin gets hot, has pus or looks bruised one or more days after your shot, call your healthcare provider.
- Headache.

Women using depo-subQ provera 104 for birth control or endometriosis had these less common side effects: abdominal pain, acne, breast tenderness, being irritable, depression, hot flushes, insomnia, joint pain, lack of energy, less sex drive, nausea and sleepiness.

If you feel you are having other side effects, talk with your healthcare provider.

#### **DOES depo-subQ provera 104 CAUSE CANCER?**

- Birth control like depo-subQ provera 104 was studied in women for many years. In general, the risk of breast cancer slightly increased or stayed about the same as in women not using birth control like depo-subQ provera 104.
- The risk of cancer of the ovary, liver, or cervix did not change.
- There is a decreased risk of cancer of the uterus (endometrial cancer).

#### **WHAT IF I WANT TO BECOME PREGNANT?**

Plan ahead. The effect of depo-subQ provera 104 can last for a long time after you stop getting shots. Although you may be able to get pregnant quickly, it is more likely to take a year or longer after your last shot before you get pregnant.

It's best to see your healthcare provider for a pre-pregnancy check-up. Your healthcare provider may also tell you to take a vitamin called folic acid every day if you are planning to become pregnant.

#### **GENERAL ADVICE ABOUT depo-subQ provera 104**

For more information about depo-subQ provera 104, ask your healthcare provider or pharmacist. You can also visit [www.depo-subQprovera104.com](http://www.depo-subQprovera104.com) or call 1-866-554 DEPO (3376). A nurse can answer questions in Spanish or English 24 hours-a-day, 7 days a week.

#### **WHAT IS IN depo-subQ provera 104?**

Active ingredient: medroxyprogesterone acetate  
 Inactive ingredients: methylparaben, propylparaben, sodium chloride, polyethylene glycol, polysorbate 80, monobasic sodium phosphate-H<sub>2</sub>O, dibasic sodium phosphate-12H<sub>2</sub>O, methionine, povidone, water for shot. When necessary, the pH is adjusted with sodium hydroxide or hydrochloric acid, or both.

**Rx only**



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