



## Patient Information

### Medroxyprogesterone Acetate (med ROX ee proe JES ter one AS e tate) Injectable Suspension, USP

Read this Patient Information carefully before you decide if medroxyprogesterone acetate injectable suspension is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about medroxyprogesterone acetate injectable suspension, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

#### What is the most important information I should know about medroxyprogesterone acetate injectable suspension?

Medroxyprogesterone acetate injectable suspension can cause serious side effects, including:

- Use of medroxyprogesterone acetate injectable suspension may cause you to lose calcium stored in your bone and decrease your bone mass. The longer you use medroxyprogesterone acetate injectable suspension, the greater your loss of calcium from your bones. Your bones may not recover completely when you stop using medroxyprogesterone acetate injectable suspension.
- If you use medroxyprogesterone acetate injectable suspension continuously for a long time (for more than 2 years), it may increase the risk of weak, porous bones (osteoporosis) that could increase the risk of broken bones, especially after menopause.
- You should not use medroxyprogesterone acetate injectable suspension for more than two years unless you cannot use other birth control methods.
- It is not known if your risk of developing osteoporosis is greater if you are a teenager or young adult when you start to use medroxyprogesterone acetate injectable suspension (see "What are the possible side effects of medroxyprogesterone acetate injectable suspension?").

Medroxyprogesterone acetate injectable suspension is intended to prevent pregnancy. Medroxyprogesterone acetate injectable suspension does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

#### What is medroxyprogesterone acetate injectable suspension?

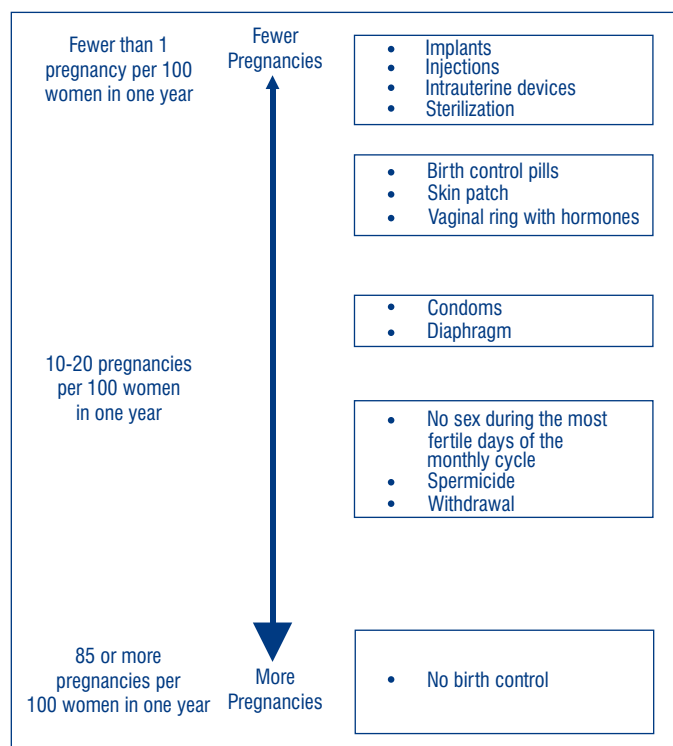
Medroxyprogesterone acetate injectable suspension is a progestin hormone birth control method that is given by injection (a shot) to prevent pregnancy.

#### How well does medroxyprogesterone acetate injectable suspension work?

Your chance of getting pregnant depends on how well you follow the directions for taking your medroxyprogesterone acetate injectable suspension. The more carefully you follow the directions (such as returning every 3 months for your next injection), the less chance you have of getting pregnant.

In clinical studies, about 1 out of 100 women got pregnant during the first year that they used medroxyprogesterone acetate injectable suspension.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



#### How should I take medroxyprogesterone acetate injectable suspension?

- Medroxyprogesterone acetate injectable suspension is given by your healthcare provider as a shot into your muscle (intramuscular injection). The shot is given in your buttock or upper arm 1 time every 3 months. At the end of the 3 months, you will need to return to your healthcare provider for your next injection in order to continue your protection against pregnancy.
- **To make sure that you are not pregnant before you take medroxyprogesterone acetate injectable suspension, the first injection should be given only:**
  - o during the first 5 days of a normal menstrual period, or
  - o within the first 5 days after giving birth, **if you are not breastfeeding, or**
  - o at the 6<sup>th</sup> week after giving birth, **if you are feeding your baby only breastmilk.**

- Medroxyprogesterone acetate injectable suspension may be given at other times than those listed above, but you will likely need to have a pregnancy test first to show that you are not pregnant.
- During treatment with medroxyprogesterone acetate injectable suspension, you should see your healthcare provider every year for a blood pressure check and other healthcare needs.

#### Who should not use medroxyprogesterone acetate injectable suspension?

Do not use medroxyprogesterone acetate injectable suspension if you:

- are pregnant or think you might be pregnant
- have bleeding from your vagina that has not been explained
- have breast cancer now or in the past, or think you have breast cancer
- have had a stroke
- ever had blood clots in your arms, legs or lungs
- have problems with your liver or liver disease
- are allergic to medroxyprogesterone acetate or any of the other ingredients in medroxyprogesterone acetate injectable suspension. See the end of this leaflet for a complete list of ingredients in medroxyprogesterone acetate injectable suspension.

#### What should I tell my healthcare provider before taking medroxyprogesterone acetate injectable suspension?

Before taking medroxyprogesterone acetate injectable suspension, tell your healthcare provider if you have:

- risk factors for weak bones (osteoporosis) such as bone disease, use alcohol or smoke regularly, anorexia nervosa, or a strong family history of osteoporosis
- irregular or lighter than usual menstrual periods
- breast cancer now or in the past, or think you have breast cancer
- a family history of breast cancer
- an abnormal mammogram (breast X-ray), lumps in your breasts, or bleeding from your nipples
- kidney problems
- high blood pressure
- had a stroke

- had blood clots in your arms, legs or lungs
- migraine headaches
- asthma
- epilepsy (convulsions or seizures)
- diabetes
- depression or a history of depression
- any other medical conditions

If you are breastfeeding or plan to breastfeed, medroxyprogesterone acetate can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take medroxyprogesterone acetate injectable suspension.

Tell your healthcare provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Medroxyprogesterone acetate injectable suspension and certain other medicines may affect each other, causing serious side effects. Sometimes the doses of other medicines may need to be changed while you are taking medroxyprogesterone acetate injectable suspension.

Some medicines may make medroxyprogesterone acetate injectable suspension less effective at preventing pregnancy, including those listed below.

#### Especially tell your healthcare provider if you take:

- medicine to help you sleep
- bosentan
- medicine for seizures
- griseofulvin
- an antibiotic
- medicine for HIV (AIDS)
- St. John's wort

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider or pharmacist before you first start taking medroxyprogesterone acetate injectable suspension or when you get a new medicine.

Follow your healthcare provider's instructions about using a back-up method of birth control if you are taking medicines that may make medroxyprogesterone acetate injectable suspension less effective.

#### What are the possible side effects of medroxyprogesterone acetate injectable suspension?

Medroxyprogesterone acetate injectable suspension can cause serious side effects, including:

- Effect on the bones: See "What is the most important information I should know about medroxyprogesterone acetate injectable suspension?" Teenage years are the most important years to gain bone strength. The decrease in calcium in your bones is of most concern if you are a teenager or have the following problems:

- bone disease
- an eating disorder (anorexia nervosa)
- a strong family history of osteoporosis
- you take a drug that can lower the amount of calcium in your bones (drugs for epilepsy or steroid drugs)
- you drink a lot of alcohol (more than 2 drinks a day)
- you smoke

If you need a birth control method for more than 2 years, your healthcare provider may switch you to another birth control method instead of using medroxyprogesterone acetate injectable suspension. If you continue using medroxyprogesterone acetate injectable suspension, your healthcare provider may ask you to have a bone test, especially if you have other risks for weak bones.

When medroxyprogesterone acetate injectable suspension is stopped, your bones may start to regain calcium. However, in a study of teenage girls who used medroxyprogesterone acetate injectable suspension for more than 2 years, their hip bones did not completely recover by 5 years after they stopped using medroxyprogesterone acetate injectable suspension. Taking calcium and Vitamin D and exercising daily may lessen the loss of calcium from your bones.

- possible increased risk of breast cancer. Women who use medroxyprogesterone acetate injectable suspension may have a slightly increased risk of breast cancer compared to non-users.
- blood clots in your arms, legs, lungs, and eyes
- stroke
- a pregnancy outside of your uterus (ectopic pregnancy). Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.
- allergic reactions. Severe allergic reactions have been reported in some women using medroxyprogesterone acetate injectable suspension.
- loss of vision or other eye problems
- migraine headaches
- depression
- convulsions or seizures
- liver problems

**Call your healthcare provider right away if you have:**

- sharp chest pain, coughing up 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)
- sudden blindness, partial or complete (indicating a possible clot in the blood vessels of the eye)
- unusually heavy vaginal bleeding
- severe pain or tenderness in the lower abdominal area
- persistent pain, pus, or bleeding at the injection site
- yellowing of the eyes or skin

- hives
- difficulty breathing
- swelling of the face, mouth, tongue or neck

**The most common side effects of medroxyprogesterone acetate injectable suspension include:**

- irregular vaginal bleeding, such as lighter or heavier menstrual bleeding, or continued spotting
- weight gain. You may experience weight gain while you are using medroxyprogesterone acetate injectable suspension. About two-thirds of the women who used medroxyprogesterone acetate injectable suspension 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 who used medroxyprogesterone acetate injectable suspension for 2 years gained an average of 8 pounds over those 2 years.
- abdominal pain
- headache
- weakness
- tiredness
- nervousness
- dizziness

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of medroxyprogesterone acetate injectable suspension. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**What other information should I know before choosing medroxyprogesterone acetate injectable suspension?**

- **Pregnancy.** When you take medroxyprogesterone acetate injectable suspension 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 medroxyprogesterone acetate injectable suspension if you are pregnant. However, medroxyprogesterone acetate injectable suspension taken by accident during pregnancy does not seem to cause birth defects.
- **Nursing Mothers.** Although Medroxyprogesterone acetate injectable suspension can be passed to the nursing baby in the breast milk, no harmful effects on babies have been found. Medroxyprogesterone acetate injectable suspension does not stop the breasts from producing milk, so it can be used by nursing mothers. However, to minimize the amount of medroxyprogesterone acetate injectable suspension that is passed to the baby in the first weeks after birth, you should wait until your baby is 6 weeks old before you start using medroxyprogesterone acetate injectable suspension for birth control.

**How will medroxyprogesterone acetate injectable suspension change my periods?**

- **Change in normal menstrual cycle.** The side effect reported most frequently by women who use medroxyprogesterone acetate injectable suspension for birth controls is a change in their normal menstrual cycle. During the first year of using medroxyprogesterone acetate injectable suspension, you might have one or more of the following changes:
  - irregular or unpredictable bleeding or spotting
  - an increase or decrease in menstrual bleeding
  - **no bleeding at all.** In clinical studies of medroxyprogesterone acetate injectable suspension, 55% of women reported no menstrual bleeding (amenorrhea) after one year of use and 68% of women reported no menstrual bleeding after two years of use.
- **Missed period.** During the time you are using medroxyprogesterone acetate injectable suspension for birth controls, you may skip a period, or your periods may stop completely. If you have been receiving your shot of medroxyprogesterone acetate injectable suspension regularly every 3 months, then you are probably not pregnant. However, if you think that you may be pregnant, see your healthcare provider.

Unusually heavy or continuous bleeding is not a usual effect of medroxyprogesterone acetate injectable suspension and if this happens you should see your healthcare provider right away.

With continued use of medroxyprogesterone acetate injectable suspension, bleeding usually decreases and many women stop having periods completely. When you stop using medroxyprogesterone acetate injectable suspension your menstrual period will usually, in time, return to its normal cycle.

**What if I want to become pregnant?**

Because medroxyprogesterone acetate injectable suspension is a long-acting birth control method, it takes some time after your last shot for its effect to wear off. Most women who try to get pregnant after using Medroxyprogesterone acetate injectable suspension get pregnant within 18 months after their last shot. The length of time you use medroxyprogesterone acetate injectable suspension has no effect on how long it takes you to become pregnant after you stop using it.

**General Information about medroxyprogesterone acetate injectable suspension**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. This leaflet summarizes the most important information about medroxyprogesterone acetate injectable suspension. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about medroxyprogesterone acetate injectable suspension that is written for healthcare providers.

**What are the ingredients in medroxyprogesterone acetate injectable suspension?**

**Active ingredient:** medroxyprogesterone acetate  
**Inactive ingredients:** polyethylene glycol 3350, polysorbate 80, sodium chloride, methylparaben, propylparaben, and water for injection. When necessary, pH is adjusted with sodium hydroxide or hydrochloric acid, or both.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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