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Medroxyprogesterone acetate: Patient drug information

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(For additional information see "Medroxyprogesterone acetate: Drug information" and see "Medroxyprogesterone acetate: Pediatric drug information")

Brand Names: US

Depo-Provera; Depo-SubQ Provera 104; Provera

Brand Names: Canada

Depo-Provera; Provera

Warning

Birth control and endometriosis pain:

• Using this drug for birth control or endometriosis pain may cause bone loss. Bone loss is greater the longer the drug is used and may not go back to normal. It is not known what the effects will be on bones when used in teenagers and young adults. Do not use this drug for longer than 2 years unless other options will not work or cannot be used.

Hormone replacement therapy (HRT):

• Do not take with estrogens to prevent heart disease or dementia. Using estrogens may raise your chances of having a heart attack, a stroke, breast cancer, a blood clot, or dementia.

• Use estrogens with or without progestin for the shortest time needed at the lowest useful dose.

What is this drug used for?

- It is used to prevent pregnancy.
- It is used to lower the chance of endometrial changes in women after change of life who are getting estrogen therapy.
- It is used to treat pain caused by endometriosis.
- It is used to treat uterine bleeding due to hormonal imbalance.
- It is used to treat endometrial cancer.
- It is used to treat kidney cancer.
- It is used to treat females who do not have a monthly period cycle.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have had any of these health problems: Bleeding disorder; blood clots or risk of having a blood clot; breast cancer or other cancer; liver disease; heart attack; stroke; or tumor where estrogen or progesterone make it grow.
- If you have unexplained vaginal bleeding.
- If you are pregnant or may be pregnant. Some forms of this drug are not for use during pregnancy.
- If you are breast-feeding or plan to breast-feed.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all uses of this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Blood clots have happened with this drug. These clots have included heart attack, stroke, and clots in the leg, lung, or eye. Sometimes blood clots can be deadly. Tell your doctor if you have ever had a blood clot. Talk with your doctor.
- Talk with your doctor if you will need to be still for long periods of time like long trips, bedrest after surgery, or illness. Not moving for long periods may raise your chance of blood clots.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.
- Liver problems have happened. Call your doctor right away if you get signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- High triglyceride levels have happened with this drug. Tell your doctor if you have ever had high triglyceride levels.
- Have a bone density test as you have been told by your doctor. Talk with your doctor.
- Take calcium and vitamin D as you were told by your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- There may be a higher chance of breast cancer.
- Be sure to have regular breast exams and gynecology check-ups. You will also need to do breast self-exams as you have been told.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- This drug may cause dark patches of skin on your face. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- If you are 65 or older, use this drug with care. You could have more side effects.

All injection products:

• If you will be trying to get pregnant, it may take some time after your last dose of this drug to get pregnant. Talk with your doctor.

Birth control and endometriosis pain:

• If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.

• If you get pregnant or have severe stomach pain while using this drug, call your doctor right away. The chance of pregnancy outside of the uterus (ectopic pregnancy) may be higher with this drug.

Birth control:

- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through having sex. Do not have any kind of sex without using a latex or polyurethane condom. If you have questions, talk with your doctor.
- Certain drugs or herbal products could cause this drug to not work as well. Be sure your doctor and pharmacist know about all of your drugs.

<u>Hormone replacement therapy (HRT):</u>

- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- There may be a higher chance of endometrial cancer.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

For all uses of this drug:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Eyesight changes or loss, bulging eyes, or change in how contact lenses feel.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Vaginal bleeding that is not normal.
- Depression or other mood changes.
- Seizures.

• This drug may cause you to swell or keep fluid in your body. Tell your doctor if you have swelling, weight gain, or trouble breathing.

<u>Cancer treatment:</u>

- Signs of a weak adrenal gland like a very bad upset stomach or throwing up, very bad dizziness or passing out, muscle weakness, feeling very tired, mood changes, not hungry, or weight loss.
- Signs of Cushing's disease like weight gain in the upper back or belly, moon face, very bad headache, or slow healing.
- High calcium levels have happened with drugs like this one in some people with cancer. Call your doctor right away if you have signs of high calcium levels like weakness, confusion, feeling tired, headache, upset stomach or throwing up, constipation, or bone pain.

Hormone replacement therapy (HRT):

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; fever with chills; bloating; or very upset stomach or throwing up.
- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Signs of low calcium levels like muscle cramps or spasms, numbness and tingling, or seizures.
- Memory problems or loss.
- Feeling confused.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

For all uses of this drug:

- Weight gain or loss.
- Headache.
- Feeling dizzy, sleepy, tired, or weak.

- Feeling nervous and excitable.
- Upset stomach or throwing up.
- Bloating.
- Change in sex interest.
- Pimples (acne).
- Hair loss.
- Hair growth.
- Enlarged breasts.
- Tender breasts.
- Vaginal bleeding or spotting.
- Stomach pain.
- Trouble sleeping.
- No period or other period (menstrual) changes.

All injection products:

• Irritation where the shot is given.

Hormone replacement therapy (HRT):

- Stomach cramps.
- Joint pain.
- Leg cramps.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

<u>Tablets:</u>

• To gain the most benefit, do not miss doses.

Injection:

• It is given as a shot into a muscle or into the fatty part of the skin.

What do I do if I miss a dose?

Tablets:

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

All injection products:

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

<u>Tablets:</u>

• Store at room temperature in a dry place. Do not store in a bathroom.

All injection products:

• Most of the time, this drug will be given in a hospital or doctor's office. If stored at home, follow how to store as you were told by the doctor.

<u>All products:</u>

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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