

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **DEPO-PROVERA**<sup>®</sup>

#### **Medroxyprogesterone acetate injectable suspension, USP**

Read this carefully before you are given **DEPO-PROVERA** and each time you receive an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DEPO-PROVERA**.

#### **Serious Warnings and Precautions**

- Low Bone Density (osteoporosis): DEPO-PROVERA may cause your bones to become less dense. This can lead to osteoporosis or broken bones. It is worse the longer you use the drug. The effect on your bones may not be reversed by stopping the drug. This is of concern because adolescence and young adulthood are times to build bone density for later in life.
- Only use DEPO-PROVERA if you and your healthcare professional decide that no other treatment will work for you.
- Use it for the shortest period of time possible.
- Your risks and benefits should be regularly re-evaluated by you and your healthcare professional.
- You should not smoke. It increases the risk of serious side effects on the heart and blood vessels.
- DEPO-PROVERA DOES NOT PROTECT against sexually transmitted infections. This includes HIV/AIDS. Use condoms (latex or polyurethane) to reduce the risk.
- Women considering using DEPO-PROVERA should be advised about the concerns that DEPO-PROVERA may increase risk of HIV acquisition, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV.

#### **What is DEPO-PROVERA used for?**

- birth control to prevent pregnancy

#### **How does DEPO-PROVERA work?**

DEPO-PROVERA works in 3 ways to make pregnancy unlikely:

- stops the maturing of the egg in the ovaries
- changes the lining of the uterus
- thickens the mucous in the cervix

DEPO-PROVERA is more than 99.7 percent effective in preventing pregnancy.

#### **What are the ingredients in DEPO-PROVERA?**

Medicinal ingredients: medroxyprogesterone acetate

Non-medicinal ingredients: methylparaben, polyethylene glycol, polysorbate, propylparaben, sodium chloride, and water for injection. It may also contain hydrochloric acid, sodium hydroxide or both.

**DEPO-PROVERA comes in the following dosage forms:**

Prefilled syringes of sterile aqueous suspension: 150 mg/mL

**Do not use DEPO-PROVERA if:**

- You are pregnant or think you might be
- Your menstrual periods have not started
- You have unusual vaginal bleeding without a known reason
- You have blood in your urine
- You have or suspect a cancer. It can be of the breast, uterus or ovaries. It can be a cancer that grows in response to progesterone.
- You have breast lumps or breast abnormalities without a known reason
- You have had blood clots in the legs, lungs, eyes or another part of the body, or inflammation of the veins (thrombophlebitis)
- You have or have had problems with your blood clotting system that increase your risk of developing blood clots (including coagulation disorders)
- You have had a stroke, heart attack, heart disease or coronary artery disease
- You have severe high blood pressure
- You have very high levels of blood cholesterol or triglycerides
- You are a heavy smoker (more than 15 cigarettes per day) and are over age 35
- You have diabetes with complications
- You have had a loss of vision due to blood vessel disease of the eye
- You have or have had migraine headaches with auras such as changes in your vision, sensations, balance, muscle coordination, or speech
- You have yellowing of the eyes or skin (jaundice), liver disease or a liver tumour
- You are allergic to medroxyprogesterone acetate or to any of the ingredients in DEPO-PROVERA

If you want to get pregnant in the near future, you should discuss other treatments with your healthcare professional. DEPO-PROVERA may not be the right treatment for you.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive DEPO-PROVERA. Talk about any health conditions or problems you may have, including if you:**

- Have a family history of breast cancer, or an abnormal breast exam or mammogram
- Have diabetes, or a family history of it
- Have seizures, convulsions or epilepsy
- Have migraine headaches
- Have asthma
- Have any heart problems
- Have kidney problems
- Have high blood pressure, or a family history of it
- Have or have had mental depression
- Have menstrual periods that are very light or that occur in an irregular pattern
- Have a history of smoking or are a current smoker
- Have a scheduled lab test or surgery
- Have a history of meningioma (tumor in tissues that cover the brain and spinal cord)

**Other warnings you should know about:**

**Sexually Transmitted Infections:** DEPO-PROVERA may increase the risk of HIV acquisition. Talk to your healthcare professional about how to minimize the risk of getting HIV.

**Low Bone Density (osteoporosis):** DEPO-PROVERA may cause your bones to become less dense. Other risk factors for low bone density are:

- bone disease
- strong family history of osteoporosis
- use of certain steroids or anti-seizure drugs
- drinking a lot of alcohol
- smoking
- low body weight or anorexia nervosa or bulimia (eating disorders)

Talk with your healthcare professional about how:

- to keep your risk as low as possible
- to strengthen your bones

**Cancer:** Use of this drug has not shown an increased risk of cancer of the liver, breast, ovary, or cervix. There is a decrease risk of cancer of the uterus.

Some women who took DEPO-PROVERA got breast cancer. This seems to occur if:

-you were under 35 years old when you took the drug.

AND

-you used the drug in the 4 years before being diagnosed with breast cancer.

Talk to your healthcare professional about breast self-examination.

**Blood clots:** Talk to your healthcare professional if you develop risk factors for blood clots. These include:

- start smoking
- obesity
- recent major surgery (such as hip or knee replacement)
- immobility due to air travel or other reason
- lupus

**Pregnancy:** You should not use DEPO-PROVERA if you are pregnant, or think that you may be pregnant. It will not prevent the pregnancy from continuing. It may interfere with the normal development of your baby.

**When might you get pregnant after stopping the injections?**

If you want to become pregnant, tell your healthcare professional. DEPO-PROVERA will not make you infertile. It takes time after the last injection for the drug's effect to wear off. Most women wait six to eight months to start ovulating and have regular periods. This must occur before you can get pregnant.

After their last injection, women get pregnant:

- within 6 months, 54%
- within 1 year, 76%
- within 2 years, 92%

It can take more than 2 years for some women to get pregnant. This does not depend on how long the drug was used.

**What if you do NOT want to get pregnant after stopping the injections?**

You must start using another method of birth control 3 months after your last injection.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with DEPO-PROVERA:**

- Aminoglutethimide: a drug used to treat [Cushing's syndrome](#).
- Rifampin: a drug used to treat tuberculosis (TB) and some other infections.

**How is DEPO-PROVERA given to patients:**

DEPO-PROVERA is given as an injection by your healthcare professional. DEPO-PROVERA is injected deep into the muscles of your buttock or upper arm.

**Usual dose:**

**For birth control:**

**First injection:**

- If your period bleeding pattern is not normal for you, have a pregnancy test first.
- Get your first injection within 5 days of starting your period. If this is followed, DEPO-PROVERA will start working on the day of the injection.
- If the injection is given after the first 5 days of your period, it may not start to protect you from pregnancy for another 3-4 weeks. During these 3-4 weeks you **MUST** use another non-hormonal birth control method.

**Ongoing Injections:**

Get an injection every 3 months. If you can't see your healthcare professional right at 3 months, you can go a week or two early.

**After a miscarriage or abortion:** Talk with your healthcare professional about when you may start using DEPO-PROVERA.

**After having a baby, if you are:**

- **NOT breastfeeding or NOT planning to breastfeed:**

Get your first injection during the 5 days after having your baby. It will start working as soon as you have the injection.

- **Breastfeeding or planning to breastfeed:**

It is recommended to wait at least 6 weeks after having your baby before you get an injection. A very small amount of drug will go into your milk. This drug should not affect the amount or quality of your milk. Talk with your healthcare professional to determine the risk to the baby or of getting pregnant.

Talk with your healthcare professional about the chance that you may get pregnant during this time. You and your healthcare professional can decide what other birth controls to use, and when you can start the drug.

**Overdose:**

If you think you, or a person you are caring for, have been given too much DEPO-PROVERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have not had an injection within 13 weeks of your last injection, you should have a pregnancy test before getting any further injections. This is in case you became pregnant in the meantime.

**What are possible side effects from using DEPO-PROVERA?**

These are not all the possible side effects you may have when taking DEPO-PROVERA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- tiredness, problems sleeping
- leg cramps, joint pain, backache
- pain in your pelvic area, lower sex drive, hot flashes, bloating
- acne
- skin reaction, pus collection, pain or tenderness at the injection site
- lump, dent, dimple, scar or change in colour at injection site (may be persistent)
- nervousness, dizziness
- no hair growth or excessive hair growth

You may gain weight because your appetite has increased. If you notice this over a short period of time, tell your healthcare professional to make a plan about what to do.

**Change in your periods:**

- more or less often
- lighter or heavier

For the first 3 to 6 months after the first injection, bleeding:

- can come and go
- can't be predicted
- can last much longer than usual

Over the next few months, bleeding:

- usually becomes lighter

After about a year, your periods:

- may stop completely

DEPO-PROVERA can cause low bone density. Your healthcare professional will decide when to perform bone density tests and interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
Abdominal pain, nausea or vomiting		√	
Headache or a migraine that gets worse		√	
<b>Depression:</b> sad mood that doesn't go away. If you have a history of depression, this drug may make your depression worse.			√
Very heavy bleeding that lasts for several days		√	
<b>Edema:</b> swelling of the arms and legs		√	
<b>UNCOMMON</b>			
Broken bones			√
<b>Osteoporosis:</b> weak bones, increased risk that your bones might break especially as you get older than 50		√	
Breast lumps, swelling and tenderness		√	
Convulsions or seizures			√
Pain or heaviness in the chest			√
<b>Allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
<b>Blood clot in the leg</b> (deep vein thrombosis): leg swelling or pain			√
<b>Blood clot in the lung:</b> sharp chest pain, coughing up blood, or sudden shortness of breath			√
<b>Blood clot in the eye:</b> sudden loss of all or part of your vision or double vision			√
<b>Stroke or blood clot in the brain:</b> a sudden severe headache, vomiting, dizziness, fainting, problems with your vision or speech, weakness,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or numbness in the face, arm or leg			
<b>Cancer of the cervix:</b> Unexpected bleeding from the vagina		√	
<b>Urinary tract Infection:</b> blood in urine. Pain when you go pee.		√	
<b>Jaundice:</b> Yellowing of the skin or eyes			√
<b>Paralysis:</b> it is hard or you are unable to move a part of your body			√
<b>UNKNOWN FREQUENCY</b>			
<b>Heart Attack:</b> gradual chest pain, tightness pressure or squeezing. Pain in the arm, jaw or back. Trouble breathing, anxiety, and sweating			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

DEPO-PROVERA will be stored by your healthcare professional.

#### If you want more information about DEPO-PROVERA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#)); the manufacturer's website at [www.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

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