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# Package Leaflet: Information for the user

## Medroxyprogesterone Acetate

### Injectable Suspension I.P. 150 mg/mL

### DEPO-PROVERA®

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**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What DEPO-PROVERA (Medroxyprogesterone Acetate) is and what it is used for
2. What you need to know before you take DEPO-PROVERA (Medroxyprogesterone Acetate)
3. How to take DEPO-PROVERA (Medroxyprogesterone Acetate)
4. Possible side effects
5. How to store DEPO-PROVERA (Medroxyprogesterone Acetate)
6. Contents of the pack and other information

#### **1. What DEPO-PROVERA (Medroxyprogesterone Acetate) is and what it is used for**

##### **What DEPO-PROVERA (Medroxyprogesterone Acetate) is**

Medroxyprogesterone Acetate is a long-acting progestational steroid (progestogen).

##### **How DEPO-PROVERA (Medroxyprogesterone Acetate) works**

##### **For birth control: DEPO-PROVERA (Medroxyprogesterone Acetate) 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

**For treatment of endometriosis:** DEPO-PROVERA (Medroxyprogesterone Acetate) helps shrink endometrium-like tissue found outside the uterus.

##### **What DEPO-PROVERA (Medroxyprogesterone Acetate) is used for**

- birth control to prevent pregnancy

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- treatment of endometriosis

## 2. What you need to know before you take DEPO-PROVERA (Medroxyprogesterone Acetate)

### Do not take DEPO-PROVERA (Medroxyprogesterone Acetate) 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 problems with your blood clotting system that increase your risk of developing blood clots
- 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 smoke 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 migraine headaches or a history of them
- 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 (Medroxyprogesterone Acetate)
- If you want to get pregnant in the near future, you should discuss other treatments with your healthcare professional. DEPO-PROVERA (Medroxyprogesterone Acetate) may not be the right treatment for you.

### Warnings and precautions

To help avoid side effects and ensure proper use, talk to your healthcare professional before you get an injection of DEPO-PROVERA (Medroxyprogesterone Acetate)

### Talk about any health conditions or problems you may have, including if you have:

- Breast cancer or family history of breast cancer, abnormal breast exam or mammogram
- Diabetes, or a family history of it
- Seizures, convulsions or epilepsy
- Migraine headaches
- Asthma
- A heart attack or other heart problems
- Stroke or blood clots (coagulation disorder)
- Kidney problems
- High blood pressure, or a family history of it
- Mental depression
- Menstrual periods that are very light or that occur in an irregular pattern
- A history of smoking or are a current smoker

- 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 (Medroxyprogesterone Acetate)** may increase the risk of HIV acquisition. Talk to your doctor about how to minimize the risk of getting HIV.
- **Low Bone Density (osteoporosis): DEPO-PROVERA (Medroxyprogesterone Acetate)** 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 doctor 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 decreased risk of cancer of the uterus.

Some women who took **DEPO-PROVERA (Medroxyprogesterone Acetate)** 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 doctor about breast self-examination.

**Blood clots:** Talk to your doctor 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

**Other medicines and DEPO-PROVERA (Medroxyprogesterone Acetate)**

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 (Medroxyprogesterone Acetate):**

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

**Pregnancy:** You should not use DEPO-PROVERA (**Medroxyprogesterone Acetate**) 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 (Medroxyprogesterone Acetate)** 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, 92% women get pregnant within 2 years.

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

### **Driving and using machines**

No data available.

### **3. How to take DEPO-PROVERA (Medroxyprogesterone Acetate)**

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

**DEPO-PROVERA (Medroxyprogesterone Acetate)** should not be injected into the veins.

**Usual dose for birth control:** The usual dose is 150mg/ml every 3 months

#### **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 (Medroxyprogesterone Acetate)** 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 (Medroxyprogesterone Acetate)**.

#### **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 doctor to determine the risk to the baby or of getting pregnant.

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

**Usual dose for endometriosis:** Treatment should be with either:

- 100 mg injection every 2 weeks for at least 6 months
- 150 mg injection every 3 months

**Overdose:**

If you think you were injected too much DEPO-PROVERA (Medroxyprogesterone Acetate), contact your healthcare professional, 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.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any side effects not listed here, contact 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 (Medroxyprogesterone Acetate)** can cause low bone density. Your doctor will decide when to perform bone density tests and interpret the results.

<b>Serious side effects and what to do about them</b>			
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, 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</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, talk to your healthcare professional.

**5. How to store DEPO-PROVERA (Medroxyprogesterone Acetate)**

- Store below 30°C
- Protect from light

**6. Contents of the pack and other information**

**What DEPO-PROVERA (Medroxyprogesterone Acetate) contains**

The active ingredient is Medroxyprogesterone acetate.

The other ingredients are Sodium Chloride; Methyl Parahydroxybenzoate; Propyl Parahydroxybenzoate; Polysorbate 80; Macrogol 3350 (Polyethylene Glycol 3350); Water for Injections; Sodium Hydroxide and/or Hydrochloric Acid (when necessary to adjust pH)

**What DEPO-PROVERA (Medroxyprogesterone Acetate) looks like and contents of the pack**

DEPO-PROVERA (Medroxyprogesterone Acetate) is available as:

1 ml glass vial (as 150 mg/ml) made up of hydrolytic glass class I and butyl rubber stopper - 1 x 1 ml vial, 25 x 1 ml vial.

1 ml single use-pre-filled disposable syringe (as 150 mg/ml) made up of: Barrel: Hydrolytic glass class I, Stopper: Butyl rubber, Tip Cap: Butyl rubber.

Pre-filled disposable syringe with separate needle.

All strengths/presentations mentioned in this document might not be available in the market.

**Manufacturer:**

M/s. Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium.

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