

Patient package insert in accordance with the Pharmacists' Regulations (Preparations)
- 1986

This medicine is dispensed with a doctor's prescription only

Provera® 5 mg

Tablets

Active ingredient

Medroxyprogesterone acetate 5 mg

A list of inactive and allergenic ingredients in the preparation is provided in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is intended to treat women over the age of 18 years.

1. **What is this medicine intended for?**

To treat cases requiring administration of exogenous progesterone.

Therapeutic group:

Progestogen, similar to the natural sex hormone progesterone.

2. **Before using the medicine**

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to other similar hormonal medicines or to any of the other ingredients contained in the medicine (listed in section 6).
- you are pregnant or think you may be pregnant. The doctor may ask you to perform a pregnancy test before starting treatment or during the treatment if your period is delayed.
- you have breast cancer or have been diagnosed with breast cancer in the past.
- you suffer from or have suffered in the past from formation of venous blood clots (venous thrombosis).
- you suffer from or have suffered in the past from formation of arterial blood clots (arterial thrombosis).
- you suffer from liver problems.
- you suffer from porphyria - when your body lacks the ability to correctly produce certain enzymes, and it manifests with either neurological complications or with skin problems (or occasionally both).

Special warnings regarding the use of the medicine

Before treatment with the medicine, tell the doctor if you have or have ever had any of the following conditions:

- Epilepsy
- Migraines
- Asthma
- Heart problems
- Kidney problems
- Diabetes
- A meningioma (a usually benign tumour that forms in the layers of tissue that cover your brain and spinal cord)
- Depression or a history of depression
- Hypertension
- Liver problems

- Gallstones
- Systemic lupus erythematosus (SLE) - an allergic condition which causes joint pain, skin rashes and fever
- Hearing problems.

Provera, especially in high doses, may cause weight gain and fluid retention.

Risk of developing venous blood clots (VTE):

All women have a small chance of having a blood clot in the veins of the leg, in the lungs or other parts of the body.

The chances of developing a clot are very slightly higher if you are taking a hormonal preparation like Provera. You are more likely to develop a blood clot, whether or not you are taking Provera, if:

- you are very overweight
- you have had a blood clot in the veins or lungs in the past
- you have relatives who have had blood clots
- you are unable to move for a long period (for example after an operation)
- you suffer from a severe injury or have undergone major surgery
- you have a history of repeated miscarriages

Inform the doctor if you have just had or are going to have an operation while still taking the medicine. (See section 4: "Side effects" for additional information about the warning signs for occurrence of blood clots).

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell the doctor or pharmacist. The effect of Provera may be altered when taken at the same time as the following medicines:

- Aminoglutethimide a medicine sometimes used in Cushing's syndrome
- Medicines for thinning the blood (e.g. warfarin)
- Medicines for treating seizures (e.g. phenobarbital, phenytoin and carbamazepine)
- Ritonavir and nelfinavir, sometimes used to treat HIV and AIDS
- Medicines for treating infections (e.g. rifampicin, rifabutin, nevirapine, efavirenz)
- Hypericum (St. John's wort), a herbal treatment for depression

Using the medicine and food

The medicine can be taken with or without a meal.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before starting treatment with this medicine.

Do not use the medicine if you are pregnant as hormonal medicines can affect the developing baby.

It is important to use another method of contraception (e.g. a condom) while taking the medicine, since Provera is not a contraceptive.

Breastfeeding

You should wait at least 6 weeks after childbirth before you start using Provera, since the medicine is transferred to breastmilk.

If you are breastfeeding, consult your doctor whether you should use another method to feed your baby.

Fertility

After finishing treatment with Provera, women may experience a delay before they succeed to become pregnant.

Driving and using machines

No effect on the ability to drive or use machines has been observed for this medicine.

Important information about some of the ingredients of this medicine

The medicine contains sucrose and lactose, which are types of sugar.

If you have been told by the doctor that you have an intolerance to certain sugars, contact the doctor before taking this medicine.

3. **How should you use the medicine?**

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose!

Take the medicine whole. Do not crush/split/chew, because the effect of these methods of administration has not been examined.

The information listed below will help you understand what the usual dosage for the treatment of certain conditions is:

Taking Provera for heavy or irregular menstrual bleeding and other period problems:

The usual dose is up to 10 mg per day for 5-10 days over 2-3 menstrual cycles. The doctor may recommend to combine the treatment with estrogen. A few days after discontinuation of treatment, you may experience bleeding like a period (breakthrough bleeding).

Taking Provera for amenorrhea (absence of menstruation):

The usual dose is up to 10 mg per day for 5-10 days over 3 consecutive menstrual cycles. In some cases, the doctor may combine the treatment with estrogen. A few days after discontinuation of treatment, you may experience bleeding like a period (breakthrough bleeding).

Taking Provera for treatment of endometriosis (when tissue from your womb is found outside the womb):

The usual dose is 10 mg 3 times a day for 90 consecutive days, starting on the first day of your period. If you have irregular spotting or bleeding during treatment, this is normal and should not raise concern.

If you do not have a period after discontinuation of treatment with Provera, inform the doctor and exclude pregnancy.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the required time, take a dose as soon as you remember, but never take two doses together!

Persist with the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. **Side effects**

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop the treatment and contact the doctor immediately if:

Rarely, Provera may cause a severe allergic reaction which can be life-threatening in some cases. You may experience some or all of the following side effects: wheezing, difficulty breathing, feeling faint, swelling of the face or tongue, hands and feet, very itchy skin rash.

If you think you are reacting badly to the medicine, seek medical help **immediately**.

If you experience any of the following symptoms, you should stop taking the medicine and contact the doctor **immediately**.

Symptoms of a **blood clot in the lungs** which may all occur together:

- Sudden, severe and sharp pain in the chest
- Coughing up blood
- Sudden shortness of breath
- Increase in the rate of heart beats

Symptoms which may indicate a **blood clot in the brain (a stroke)**:

- An unusually severe or persistent headache
- Any changes in your vision
- Difficulty speaking
- Collapsing or fainting
- Weakness or numbness in any part of your body

Symptoms of **deep-vein thrombosis (DVT) in the leg:**

- Severe pain, tenderness or swelling in your calf, ankle or foot
- Purple discolouration of the skin of the leg or the skin becomes red and warm to touch

Tell the doctor if you experience any of the following additional side effects:

Very common side effects - affect more than 1 in 10 users

- headache
- nausea
- unexpected or unusual vaginal spotting or bleeding

Common side effects - affect 1-10 in 100 users

- severe allergic reaction to the medicine (e.g. wheezing, difficulty breathing)
- depression
- difficulty sleeping
- nervousness
- dizziness
- hair loss
- acne
- nettle rash or hives
- itchy skin
- vaginal discharge
- breast pain
- breast tenderness
- fever
- tiredness
- weight gain

Uncommon side effects affect 1-10 in 1,000 users

- facial hair growth
- milky discharge from the breasts when not pregnant or breastfeeding
- edema/fluid retention

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- severe allergic reaction (anaphylactic reaction)
- swelling in the face/throat which may cause breathing difficulties
- delayed ovulation with longer menstrual cycle
- drowsiness
- swelling in the veins due to blood clots
- tenderness or swelling in the calf, ankle or foot
- rash
- stopping or extended break of your periods
- abnormality of cervix
- decreased sugar tolerance
- weight loss

If a side effect has appeared, if one of the side effects worsens, or when you suffer from a side effect that has not been mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. **How should the medicine be stored?**

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store the medicine below 25°C.

6. **Additional information**

In addition to the active ingredient, the medicine also contains:

Lactose, maize starch, talc, sucrose, calcium stearate, liquid paraffin (mineral oil), FD&C blue No.2 aluminium lake.

What does the medicine look like and what is the content of the package:

A round, light blue tablet, with the letter "U" imprinted on one side and the number "286" on the other side on both sides of a score line.

The medicine is available in a bottle pack containing 24 tablets **or** in a blister pack containing 100 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Provera 5 mg: 127.15.22148

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