

**Patient leaflet: Information for the user**  
**Provera® 100mg Tablets**  
Medroxyprogesterone acetate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- 1. What Provera is and what it is used for**
- 2. What you need to know before you take Provera**
- 3. How to take Provera**
- 4. Possible side effects**
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**1. What Provera is and what it is used for**

- This medicine contains medroxyprogesterone acetate, which belongs to a group of medicines called 'Progestogens'. Progestogens act like progesterone, a natural sex hormone
- Medroxyprogesterone acetate can slow down the growth of certain tumours which are sensitive to hormones.
- Provera is used in the treatment of cancer in the breast, kidney (in men and women) and in the lining of the womb (endometrial cancer) in post menopausal women (women who have stopped having their periods).
- If you are not certain why you are being given this medicine, ask your doctor.
- You must talk to a doctor if you do not feel better or if you feel worse.

**2. What you need to know before you take Provera**

**Do not use Provera:**

- If you are hypersensitive (allergic) to Provera or other similar hormone medicines or any of the other ingredients of this medicine (listed in section 6)
- If you have liver problems
- If you have undiagnosed vaginal bleeding
- If you have had blood clot disorders, including deep vein thrombosis (DVT), pulmonary embolism (clots in the lung), thrombophlebitis (inflammation of the blood vessels) or if you have been told that you are at risk of developing these conditions
- If you are pregnant or think you may be pregnant

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse if you have any of the following conditions to help him or her decide if Provera is suitable for you:

- fluid retention
- diseases that affect the heart and blood vessels (cardiovascular disease)
- epilepsy

- migraine headaches
- sudden vision disturbance
- asthma
- kidney problems
- diabetes
- depression or a history of depression
- if you are taking or have recently taken any other medicines, even those not prescribed
- jaundice (a condition which causes the skin or whites of the eye to appear yellow)
- high blood pressure
- hormonal imbalance.

### **Risk of Venous Thromboembolism (VTE)**

All women have a small chance of having a blood clot in the veins of the leg, in the lung or other parts of the body. The chances of getting a clot are very slightly increased if you are taking a hormone medicine like Provera. You are more likely to get a clot whether or not you are taking Provera if you

- are very overweight
- have relatives who have had blood clots
- have had a blood clot in the veins or lungs before
- are unable to move for long periods of time ( for example after an operation)
- have a serious injury or have major surgery
- have a history of repeated miscarriage.

Tell your doctor if you have just had an operation or if you are going to have an operation while taking Provera.

(See section 4 on 'Possible side effects' for more information on the warning signs of blood clots).

Treatment with Provera may cause you to have symptoms associated with Cushing's syndrome such as facial puffiness, weakness or weight gain.

### **Other medicines and Provera:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some drugs may affect the action of Provera in your body. Tell your doctor or pharmacist if you are taking:

- aminoglutethimide sometimes used in Cushing's syndrome
- anticoagulants like warfarin for thinning the blood

### **Pregnancy**

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Provera must not be taken if you are pregnant as medicines containing hormones may affect the developing baby. Tell your doctor if you have missed a period during treatment. Your doctor may give you a pregnancy test before starting treatment. If you are sexually active, you are advised to use effective birth control to prevent pregnancy while taking Provera.

### **Breast-feeding**

If you are breastfeeding, speak to your doctor who will advise whether you should use an alternative method of feeding your baby.

Ask your doctor or pharmacist for advice before taking any medicine while breast-feeding.

### **Driving and using machines**

There are no special precautions, and you can drive or operate machines as long as you feel well and able to do so.

**Laboratory Tests:**

Please inform your doctor if you need to have any blood tests or gynaecological assessment, as Provera may affect their results.

**3. How to take Provera**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will be closely monitored and regularly assessed before and during your treatment with Provera, especially if you are prescribed large doses of the tablet.

**Cancer of the Endometrium (womb lining) and Kidney:**

The usual dose is 200mg to 400mg a day.

**Breast Cancer:**

The usual dose is 400mg to 800mg a day. Doses of up to 1000mg daily have been given although the chance of having a minor side effect, such as weight gain, increases as the dose increases.

Swallow each tablet whole. Take your tablets at the same time each day. Follow your doctor's instructions. These can be found in the label of your pack. If you are not sure ask your doctor.

Treatment may be required for 8 to 10 weeks before any effect can be found.

**If you take more Provera than you should**

If you take too many Provera tablets, contact your doctor straight away.

**If you forget to take Provera**

If you forget to take your dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Provera**

Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first. It is important to keep taking your medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause some side effects although not everybody gets them. If they occur, they are most likely to be minor and temporary. If you get any of the symptoms mentioned below, you should **stop taking** the tablets and see your doctor **immediately**.

**Reasons for seeking immediate medical advice**

Rarely, Provera may cause a severe allergic reaction which can be life-threatening in some cases. If you think you are reacting badly to the medicine get emergency medical help **immediately**.

A severe allergic reaction to a drug may cause one or more of the following:

- wheezing
- difficulty breathing
- feeling faint
- swelling of the face or tongue
- swelling of the hands and feet

- intense itchy skin rash

These are symptoms of a **blood clot in the lungs** which may all occur together:

- Sudden, severe, sharp pain in your chest
- Coughing up blood
- You suddenly become short of breath
- Your heart beats more rapidly

These can be symptoms of a **blood clot in the brain ('a stroke')**:

- You have an unusually severe or long headache
- Your sight is affected in any way
- You find it difficult to speak
- You collapse or faint
- Any part of your body feels weak or numb or cannot move

These are symptoms of a **deep-vein thrombosis (DVT)**:

- You have pain, tenderness or swelling in your calf, ankle or foot
- You have purple discolouration of the skin of the leg or the skin becomes red and warm to touch.

#### **Reasons for stopping Provera immediately**

Your treatment will be discontinued if you have any of the following symptoms:

- yellowing of the skin or whites of the eyes or liver problems
- a significant increase in blood pressure
- new onset of migraine-type headache.

**Tell your doctor if you get any other side effects reported with Provera which may include the following:**

**Common:** may affect up to 1 in 10 people

- weight fluctuation
- lack/increased of appetite
- headache
- dizziness
- tremors
- vomiting
- constipation
- feeling sick
- excessive sweating
- impotence
- fluid retention
- tiredness

**Uncommon:** may affect up to 1 in 100 people

- Cushingoid syndrome (e.g. puffiness, weight gain)
- increase in symptoms of diabetes mellitus
- raised blood calcium levels (hypercalcaemia)
- depression
- euphoria (a state of extreme well-being and pleasure)
- changes in libido (sex drive)
- heart failure
- blood clots, including clots in the lung
- diarrhoea

- dry mouth
- swelling in face/throat which may cause difficulty breathing
- acne
- facial hair growth
- unexpected or unusual vaginal bleeding or spotting
- breast pain and tenderness
- muscular cramps

**Rare:** may affect up to 1 in 1,000 people

- severe allergic reaction to the drug (e.g. wheezing, difficulty breathing)
- nervousness
- difficulty speaking
- stroke (e.g. drooped face, weak/numb arm)
- drowsiness
- heart attacks
- swelling in the veins due to blood clots
- purple discolouration of the skin of the leg or the skin becomes red and warm to touch
- pain, tenderness or swelling in your calf, ankle or foot
- yellowing of the skin
- hair loss
- rash
- general discomfort and/or weakness
- fever
- decreased sugar tolerance
- significant increase in blood pressure

**Not known:** frequency cannot be estimated from the available data

- severe allergic reaction (anaphylactic reaction)
- delayed egg release with longer menstrual cycle (periods)
- confusion
- loss of concentration
- heart beats more rapidly
- effects like fine hand tremors
- blocked retinal blood vessels may cause loss of vision or vision disorders
- problem with the lens of the eye due to diabetes (diabetes cataract)
- double vision
- nettle rash or hives
- itchy skin
- glucose present in urine
- stopping or extended break of your periods and vaginal discharge
- abnormality of cervix
- milky discharge from the breast when not pregnant or breastfeeding
- yellowing of the skin or whites of the eyes or liver problems
- raised white blood cells and platelet

In women who have not yet gone through menopause, Provera may cause a decrease in bone density (particularly when taken for more than 2 years). This may lead to an increased risk of developing osteoporosis (brittle bones) later in life. You should ensure that you have sufficient calcium and Vitamin D in your diet. Ask your doctor if you are unsure.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Provera**

- The unopened bottles should be stored in the original container until ready for use.
- Do not store above 25°C.
- Keep this medicine out of the sight and reach of children.
- Provera should not be used after the expiry date printed on the box and on the bottle label after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Provera tablets contains**

Each Provera Tablet contains 100 mg of the active ingredient medroxyprogesterone acetate. Provera Tablets also contain the following inactive ingredients: microcrystalline cellulose, maize starch, gelatin, macrogol 400, sodium starch glycollate, docusate sodium, sodium benzoate and magnesium stearate.

### **What Provera tablets look like and contents of the pack**

Provera tablets are white, round flat tablets marked 'U-467' on one side and scored on the other. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Provera Tablets are available in the following pack sizes:

- 30, 60 and 100 tablets in blister strips.
- Amber glass bottle containing 100 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder:**

Pfizer Healthcare Ireland,  
9 Riverwalk,  
National Digital Park,  
Citywest Business Campus,  
Dublin 24,  
Ireland

### **Manufacturer:**

Pfizer Italia S.r.l.,  
Localita Marino del Tronto,  
63100 Ascoli Piceno (AP),  
Italy.

### **Company Contact Address:**

For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland Telephone 1800 633 363

This leaflet was last revised in 09/2015.

Ref: PV HD 8\_4