

## **Package leaflet: Information for the patient**

### **Provera® 2.5mg, 5mg and 10mg Tablets** Medroxyprogesterone acetate

*Pfizer*

**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**
- 5. How to store Provera**
- 6. Contents of the pack and other information**

#### **1. What Provera is and what it is used for**

- Provera contains the active substance medroxyprogesterone acetate which is one of a group of medicines called 'progestogens'. Progestogens are similar to the natural female hormone, progesterone.
- Provera has several uses. You can take Provera to treat or manage:
  - heavy periods
  - painful periods
  - irregular periods or periods that are more frequent than normal
  - absence of periods
  - mild to moderate endometriosis (where tissue from your womb is found outside your womb)
  - to protect the womb lining during treatment with oestrogens in women after the menopause.

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**

**Provera may not be suitable for all women. Please read the following list carefully to see if any of these apply to you. Consult your doctor if you are not sure.**

##### **Do not take Provera if you:**

- are allergic to medroxyprogesterone acetate or other similar hormone medicines, or to any of the other ingredients of this medicine (listed in section 6)
- are pregnant, or think you might be pregnant. Your doctor will ask for a negative pregnancy test before starting treatment or if you miss a period during treatment
- have now or have ever had any vaginal bleeding (not a period) for which your doctor could not find a cause
- have now or have had in the past any cancers of the genitals or breast
- have liver problems
- have suffered in the past or recently from blood clots in the lungs or legs (thromboembolism) or any condition related to blood clots such as a stroke or a heart attack

- have porphyria where your body lacks the ability to correctly produce certain enzymes and it manifests with either neurological complications or with skin problems (or occasionally both).

### **Warnings and precautions**

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

- epilepsy
- migraine headaches
- asthma
- heart problems or high blood pressure
- kidney problems
- diabetes
- depression or a history of depression
- liver problems
- hearing problems
- fibroids in the uterus (leiomyoma)
- a condition called lupus erythematosus (a disorder characterised by skin inflammation)
- if you have a family history of breast cancer and are at risk of developing breast cancer
- a history of endometrial hyperplasia (abnormal growth on your womb)
- cholelithiasis (gallstone).

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

### **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 part of the body. The chances of getting a clot are very slightly higher 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 had a blood clot in the veins or lungs before
- have relatives who have had blood clots
- 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. Section 4 of this leaflet 'Possible side effects' also has more information on the warning signs of blood clots.

### **Risk of Breast and Ovarian Cancer**

It has been noted from studies, that women who are on long term use (5-10 years) on medicines that contain oestrogens and oestrogen-progesterone combinations (commonly associated with hormone replacement therapy medicines) do have an increased risk of developing breast and ovarian cancer. However the risk does fall and return to normal levels within a few years (at most 5) after stopping treatment.

### **Provera Tablets contain lactose monohydrate, sucrose and sunset yellow (E110)**

Lactose monohydrate and sucrose are types of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Provera 2.5 mg tablets also contain the colour E110 which may cause allergic reactions, particularly in those who are allergic to aspirin.

### **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. The effect of Provera may be altered when they are taken at the same time as any of the following medicines:

- anticonvulsants like phenobarbitol, phenytoin, carbamazepine for epilepsy (fits)
- anti-infective medicines like rifampicin and rifabutin for infections caused by bacteria
- anti-virals such as, efavirenz, nevirapine, ritonavir or nelfinavir to treat infections caused by viruses
- herbal preparations containing St. John's Wort
- aminoglutethimide, sometimes used in Cushing's Syndrome
- medicines for thinning the blood (e.g. warfarin).

### **Pregnancy, breast-feeding and fertility**

#### **Pregnancy**

If you are pregnant, 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 can affect the developing baby. Tell your doctor if you think you may be pregnant. It is important you use another method of contraception (e.g. a condom) while taking Provera, as it is not a contraceptive.

#### **Breast-feeding**

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

#### **Driving and using machines**

No effect on the ability to drive or use machines has been seen with Provera.

#### **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. The number of tablets will depend on the condition you are being treated for. This information can also be found on the label on the box the tablets come in. The following information will help you see what the usual dose is for a particular problem.

#### **Length of treatment**

Your doctor will ask you to come back for a check up after a few months to review your treatment and to discuss the benefits and risks to you. Your doctor will aim to give you the lowest dose for the shortest time needed to treat your symptoms.

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

You will usually take 2.5mg-10mg for 5-10 days beginning 16 days to 21 days after your last period began. Treatment should be given for 2 consecutive cycles. In some cases, your doctor may also prescribe oestrogen to be taken at the same time as Provera at doses of 5-10mg for 10 days. A few days after you stop taking the tablets you may have bleeding like a period (breakthrough bleeding).

**Taking Provera when you have amenorrhoea (when you are not having periods):**

You will usually take 2.5mg-10mg for 5-10 days beginning on a day which has been calculated or assumed to represent Day 16 to Day 21 of your menstrual cycle. Repeat the treatment for 3 consecutive cycles. In some cases, your doctor may also prescribe oestrogen to be taken at the same time as Provera for 10 days. A few days after you stop taking the tablets you may have bleeding like a period (breakthrough bleeding).

**Taking Provera for endometriosis (where tissue from your womb is found outside your womb):**

- You will usually take 10mg 3 times a day (30mg) for 3 months (90 days) starting on the first day of your period. If you have any irregular spotting or bleeding during treatment this is normal and nothing to worry about.

**Taking Provera to protect your womb lining during treatment with oestrogens:**

You will usually take 10mg each day for 10-12 days beginning on the 16<sup>th</sup> day of a 28 day course of oestrogen therapy. Your period should occur 3 to 7 days after starting Provera.

**If you do not have a period after you finish a course of Provera, check with your doctor in case you are pregnant.**

**If you forget to take Provera**

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times. **Do not take a double dose to make up for a forgotten dose.**

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

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

**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 side effects, although not everyone gets them.

**Reasons for stopping Provera treatment immediately**

- Rarely, Provera may cause a severe allergic reaction which can be life-threatening in some cases. You can get some or all of the following symptoms: wheezing, difficulty breathing, feeling faint, swelling of the face or tongue, hands and feet, intense itchy skin rash. If you think you are reacting badly to the medicine get emergency medical help **immediately**.
- Please report any unusual vaginal bleeding, loss of vision or if there is a sudden onset of enlarged eyeball, double vision or migraine or significant changes in blood pressure.
- The onset of jaundice (yellowing of the skin or whites of the eyes).
- If you become pregnant.

If you get any of the following symptoms, you should **stop taking** the tablets and see your doctor **immediately**.

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

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

- You have severe 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

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

Very common: may affect more than 1 in 10 people

- headache
- feeling sick
- unexpected or unusual vaginal bleeding or spotting

Common: may affect up to 1 in 10 people

- severe allergic reaction to the drug (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 increase

Uncommon: may affect up to 1 in 100 people

- Facial hair growth
- milky discharge from the breast when not pregnant or breastfeeding
- oedema/fluid retention

Not known: frequency cannot be estimated from the available data

- severe allergic reaction (anaphylactic reaction)
- swelling in face/throat which may cause difficulty breathing
- delayed egg release with longer menstrual cycle (periods)
- drowsiness
- swelling in the veins due to blood clots

- tenderness or swelling in your calf, ankle or foot
- yellowing of the skin or whites of the eye (jaundice)
- rash
- stopping or extended break of your periods
- abnormality of cervix
- decreased sugar tolerance
- weight decrease

### **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**

Provera tablets should not be used after the expiry date printed on the carton or blister strip or bottle after EXP. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C, and keep your blister strips securely in the outer carton. Keep this medicine out of the sight and reach of children.

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 looks like and contents of the pack**

**Provera 2.5 mg** tablets are orange round tablets scored on one side and marked 'U64' on the other. They are available in packs of 30 or 100 tablets.

**Provera 5mg** tablets are pale blue round tablets scored on one side, with '286' either side of the score and marked 'U' on the other side. They are available in packs of 10, 20, 30, 50 or 100 tablets.

**Provera 10mg** tablets are white, round, convex tablets scored on one side, and marked 'UPJOHN 50' on the other side. They are available in packs of 10, 20, 50, 90 or 100 tablets.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Not all pack sizes may be marketed.

### **What Provera Tablets contains**

The active substance is medroxyprogesterone acetate, Each tablet contains either 2.5mg, 5mg or 10mg of medroxyprogesterone acetate.

The other ingredients are:

- 2.5 mg: Lactose monohydrate, sucrose, maize starch, liquid paraffin, talc, calcium stearate, the colour Sunset yellow FCF (E110).
- 5 mg: Lactose monohydrate, maize starch, sucrose, liquid paraffin, calcium stearate, talc, the colour FD & C Blue No. 2 (E132).
- 10 mg: Lactose monohydrate, sucrose, maize starch, liquid paraffin, talc, calcium stearate.

**Please see section 2 Provera contain lactose monohydrate, sucrose and sunset yellow (E110).**

**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

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It is often useful to share your problems with other women. You may find a local self-help group or contact one of the organisations below:

**The National Endometriosis Society** 50 Westminster Palace Gardens, Artillery Row,  
London, SW1 1RR  
Help-line number: 00 44 207 2222776

**Irish Menopause Society** President, Dr Barbara O' Beirne, 6 The Crescent, Galway  
Telephone: 091 583268