

## Patient Information Leaflet

### Provera™ 2.5mg, 5mg and 10mg Tablets Medroxyprogesterone acetate

#### Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### 1. What Provera Tablets are and what they are used for

- Provera Tablets are one of a group of medicines called 'progestogens'. Progestogens are similar to the natural female hormone progesterone. Provera contains the progestogen called medroxyprogesterone acetate as the active ingredient.
- 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)

#### 2. Before you take Provera Tablets

**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 Provera tablets (see Section 6 'Further information' for more details)
  - are pregnant, or think you might be pregnant. Your doctor may give you a 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

- **Taking special care with Provera**

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

- Epilepsy
- Migraine headaches
- Asthma
- Heart problems
- Kidney problems
- Diabetes
- Depression or a history of depression

**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.

**Important information on some of the ingredients of Provera**

Provera Tablets contain lactose and sucrose which 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

**Taking other medicines**

Tell your doctor or pharmacist if you are taking any of the following medicines, as the effect of Provera may be altered when they are taken at the same time:

- Aminoglutethimide, sometimes used in Cushing's Syndrome
- Medicines for thinning the blood (e.g warfarin)

Tell your doctor or pharmacist if you are taking any other medicines not listed above, including those bought without a prescription.

**Pregnancy**

Provera must not be taken if you are pregnant as hormonal medicines can affect the developing baby. It is important you use another method of contraception (eg a condom) while taking Provera, as it is not reliable as a contraceptive.

### **Breastfeeding**

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

### **Driving and using machinery**

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

## **3. How to take Provera Tablets**

You should follow your doctor's instructions carefully. 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.

### **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 after your last period began. A few days after you stop taking the tablets you will usually have bleeding like a period.

To stop your periods causing problems again, your doctor may tell you to repeat this dose of Provera during your next cycle. In some cases, your doctor may also prescribe estrogen to be taken at the same time as Provera at doses of 5-10mg for 10 days.

### **Taking Provera 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 of your menstrual cycle. A few days after you stop taking the tablets you will usually have bleeding like a period.

Your treatment will be repeated for three cycles. In some cases, your doctor may also prescribe estrogen to be taken at the same time as Provera at doses of 5-10mg for 10 days.

**Taking Provera for endometriosis** - 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.

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

### **What do I do if I forget to take a tablet?**

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times.

### **What if I take too many tablets at once?**

If you take too many tablets, contact your doctor straight away. Make sure that nobody else takes your tablets.

## **4. Possible Side Effects**

Like all medicines Provera 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** .

If you get any of the following symptoms, you should **stop taking** the tablets and see your doctor **immediately**. These could all be warning signs of thrombosis (a blood clot) which will need urgent treatment.

:

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

These are symptoms of a blood clot in the lungs

- 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 can be symptoms of a blood clot in the brain ('a stroke')

- 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

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

### **Other side effects**

You can also get the following side effects with medicines like Provera:

**Effects on the reproductive system and breasts:** breast pain and tenderness, a milky discharge from the breast when not pregnant or breastfeeding (galactorrhoea).

**Effects on the nervous system:** headache, depression, dizziness, fatigue, difficulty sleeping, feeling sleepy, nervousness.

**Effects on the stomach and intestines:** feeling sick.

**Effects on your heart and circulation:** blood clots, including clots in the lung, and swelling in the veins due to blood clots, stroke, heart attacks.

**Effects on your skin, nose, throat or hair:** generalised itching, rash, hives, acne, excessive hair growth on the face or body, hair loss.

**Miscellaneous:** fluid retention and swelling of hands and ankles, weight changes, decreased tolerance to sugars like glucose.

**If you experience any of the above side effects or notice any other unusual effects not mentioned in the leaflet, tell your doctor at once.**

## **5. Storing Provera Tablets**

Provera tablets should not be used after the expiry date printed on the carton or blister strip. Do not store your tablets above 25°C, and keep your blister strips securely in the

outer carton. As with all medicines, keep the tablets out of the sight and reach of children.

## 6. Further Information

### What Provera looks like and contents of the pack

**Provera 2.5 mg** tablets are orange and are available in packs of 30 tablets.

**Provera 5mg** tablets are blue and are available in packs of 10 or 100 tablets.

**Provera 10mg** tablets are white and are available in packs of 10, 90 or 100 tablets.

### What Provera Tablets contains

The active ingredient is medroxyprogesterone acetate, the tablets also contain the following inactive ingredients:

2.5 mg: Lactose monohydrate, Sucrose, maize starch, liquid paraffin, talc, calcium stearate, the colour E110, purified water

5 mg: Lactose monohydrate, starch, sucrose, liquid paraffin, calcium stearate, talc, the colour FD & C Blue No. 2 Aluminium Lake, purified water.

10 mg: Lactose monohydrate, sucrose, maize starch, liquid paraffin, talc, calcium stearate.

**Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

**Manufacturer:** Pharmacia and Upjohn SpA, Via del Commercio 63046, Marino del Tronto, Italy.

### Company Contact Address:

For further information on your medicine please contact Medical Information at the following address: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, Tel 01304 616161.

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