

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
PROVERA® 5mg TABLETS / PROVERA® 10mg TABLETS
(medroxyprogesterone acetate)

This product is available using any of the above names but will be referred to as Provera Tablets throughout the following leaflet. Please note that the leaflet also contains information about other strength (Provera 2.5mg Tablets). **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 Tablets are and what they are used for
2. What you need to know before you take Provera Tablets
3. How to take Provera Tablets
4. Possible side effects
5. How to store Provera Tablets
6. Contents of the pack and other information

1. WHAT PROVERA TABLETS ARE AND WHAT THEY ARE USED FOR

- Provera Tablets 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 Tablets has several uses. You can take Provera Tablets 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)

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 TABLETS

Provera Tablets 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 Tablets 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 may give you a pregnancy test before starting treatment or if you miss a period during treatment
- have now or have had in the past breast cancer
- have now or have had in the past blood clots forming in your veins (venous thrombosis)
- have now or have had in the past blood clots forming in your arteries (arterial thrombosis)
- have liver problems
- 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 or pharmacist before taking Provera Tablets if you have or have ever had any of the following conditions to help them decide if Provera Tablets are suitable for you:

- Epilepsy
- Migraine headaches
- 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
- High blood pressure
- Liver problems
- Gallstones
- Systemic lupus erythematosus (SLE) = an allergic condition which causes joint pain, skin rashes and fever
- Hearing problems

Provera Tablets, 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 Tablets. You are more likely to get a clot whether or not you are taking Provera Tablets 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 Tablets. Section 4 of this leaflet 'Possible side effects', also has more information on the warning signs of blood clots.

Other medicines and Provera Tablets

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 Tablets may be altered when taken at the same time as any of the following medicines:

- Aminoglutethimide, sometimes used in Cushing's syndrome
- Medicines for thinning the blood (e.g. warfarin)
- Medicines for treating convulsions (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)
- St John's wort, a herbal treatment for depression

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 Tablets 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 (e.g. a condom) while taking Provera Tablets, as it is not a contraceptive.

Breast-feeding

You should wait at least 6 weeks after your baby has been born before you start using Provera Tablets as it is transferred to breastmilk. If you are breast-feeding, speak to your doctor who will advise whether you should use an alternative method of feeding your baby.

Fertility

After finishing treatment with Provera Tablets women may experience a delay before they are able to become pregnant.

Driving and using machines

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

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

Lactose 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 sunset yellow (E110) which may cause allergic reactions.

3. HOW TO TAKE PROVERA TABLETS

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.

Taking Provera Tablets 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 Tablets 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 Tablets 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 Tablets for 10 days. A few days after you stop taking the tablets, you may have bleeding like a period (breakthrough bleeding).

Taking Provera Tablets 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.

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

If you forget to take Provera Tablets

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 Tablets than you should

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

If you stop taking Provera Tablets

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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Reasons for stopping Provera Tablets treatment immediately

Rarely, Provera Tablets 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 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 Tablets 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
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE PROVERA TABLETS

- **Keep the tablets out of the sight and reach of children.**
- Provera Tablets should not be used after the expiry date printed on the carton or blister strip. 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.
- If the tablets become discoloured or show signs of any deterioration, you should seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Provera Tablets contain

The active ingredient is medroxyprogesterone acetate. In addition to the active ingredient, the tablets also contain the following inactive ingredients:

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

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

What Provera Tablets looks like and contents of the pack

Provera 5mg tablets are blue tablets scored on one side, with ‘286’ either side of the score and marked ‘U’ on the other side.

Provera 10mg tablets are white, round tablets scored on one side and ‘UPJOHN 50’ on the other side. Provera Tablets are available in packs of 10 and 30 tablets.

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Provera® 10mg Tablets



PLGB: 15814/1381

Provera® 5mg Tablets

This product is manufactured by Pfizer Italia S.r.l. - Ascoli Piceno Plant, Via del Commercio – Zona Industriale, 63046 Marino del Tronto, Italy **OR** Pharmacia Italia S.p.A- Ascoli Piceno Plant, Via del Commercio- Zona Industriale, 63046, Marino del Tronto, Italy **OR** Pfizer Italia S.r.l., Localita Marino del Tronto, 63100 Ascoli Piceno, Italy.

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For any information about this medicine, please contact the Product Licence holder:

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