Package leaflet: Information for the patient

Medroxyprogesterone Acetate
2.5 mg, 5 mg and 10 mg 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

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1. What Medroxyprogesterone Acetate Tablets are and what they are used for
- This medicine 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.
- Medroxyprogesterone acetate has several uses. You can take this medicine 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 Medroxyprogesterone Acetate Tablets
Medroxyprogesterone acetate 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 this medicine 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 Medroxyprogesterone Acetate Tablets if you have or have ever had any of the following conditions to help them decide if this medicine is 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

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

Other medicines and Medroxyprogesterone Acetate
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 Medroxyprogesterone Acetate 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.
Medroxyprogesterone Acetate 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 this medicine, 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 Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate.

This medicine contains 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.
Medroxyprogesterone Acetate 2.5 mg Tablets also contain sunset yellow (E110) which may cause allergic reactions.

3. How to take Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate when you have amenorrhoea (when you are not having periods)
You will usually take 2.5 mg-10 mg 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 Medroxyprogesterone Acetate for 10 days. A few days after you stop taking the tablets, you may have bleeding like a period (breakthrough bleeding).

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Taking Medroxyprogesterone Acetate 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 Medroxyprogesterone Acetate, check with your doctor in case you are pregnant.

If you forget to take Medroxyprogesterone Acetate
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 Medroxyprogesterone Acetate than you should
If you take too many tablets, contact your doctor straight away.

If you stop taking Medroxyprogesterone Acetate
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 Medroxyprogesterone Acetate treatment immediately
Rarely, this medicine 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 medroxyprogesterone acetate 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 Medroxyprogesterone Acetate Tablets
Keep this medicine out of the sight and reach of children.
Medroxyprogesterone Acetate Tablets should not be used after the expiry date which is stated on the carton, blister strip or bottle label after EXP. The expiry date refers to the last day of that month.
For the blister and carton presentation, do not store your tablets above 25°C.
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 this medicine looks like and contents of the pack
Medroxyprogesterone Acetate 2.5 mg Tablets are orange and are available in blisters containing 10, 30, 50, or 100 tablets or in bottles containing 100 tablets.
Medroxyprogesterone Acetate 5 mg Tablets are blue and are available in packs of 10, 20 or 100 tablets or in bottles containing 100 tablets.
Medroxyprogesterone Acetate 10 mg Tablets are white and are available in packs of 10, 20, 30, 50, 90 or 100 tablets or in bottles containing 50 tablets.

Not all pack sizes may be marketed.

What Medroxyprogesterone Acetate Tablets contain
The active substance is medroxyprogesterone acetate. Each tablet contains either 2.5 mg, 5 mg or 10 mg medroxyprogesterone acetate.
The other ingredients are:
2.5 mg: Lactose monohydrate, sucrose, maize starch, liquid paraffin, talc, calcium stearate, sunset yellow (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, purified water.

This medicine contains lactose monohydrate, sucrose and sunset yellow (E110).

Marketing Authorisation Holder and Manufacturer

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

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

Company Contact Address:
For further information on your medicine, please contact Medical Information, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK.
Telephone: 01304 616161.

This leaflet was last revised in 03/2025.

Ref: PV LD 12_1t

PAA233148