Package leaflet: Information for the user

Provera® 100 mg Tablets
Provera® 200 mg Tablets
Provera® 400 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 or pharmacist. 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
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1. What Provera Tablets are and what they are used for

- This medicine contains medroxyprogesterone acetate, which is one of 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 tablets are used in the treatment of cancer in the breast, kidney (in men and women) and in the lining of the womb (endometrial cancer). It is also used to treat cancer which has spread to other parts of the body (metastatic cancer) in post-menopausal women (women who have stopped having their periods).
- It is not expected that Provera Tablets will be used in children for the above indications. 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 Tablets

Do not take Provera Tablets:
- If you are hypersensitive (allergic) to medroxyprogesterone acetate 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 a heart condition where you feel pain in your chest when you exert yourself (angina) or have had a heart attack or if you have been told that you are at risk of developing cardiovascular diseases
- If you have raised levels of calcium in the blood (hypercalcaemia) associated with metastasised bone cancer
- If you have suspected or recently diagnosed breast cancer for the first time

- If you have undiagnosed vaginal bleeding
- If you have past or recent blood clot disorders, including deep vein thrombosis (DVT), pulmonary embolism (clot(s) 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 have a history of a condition known as porphyria (a hereditary blood disorder)
- If you have a missed abortion (where the woman's body does not expel the dead foetus), miscarriage or pregnancy.

Warnings and precautions
Talk to your doctor or pharmacist if you have or have ever had any of the following conditions to help him or her decide if Provera Tablets are suitable for you:
- fluid retention
- diseases that affect the heart and blood vessels (cardiovascular disease)
- epilepsy
- migraine headaches
- sudden vision disturbance
- asthma
- liver or 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
- hyperlipidaemia (raised levels of fat in the blood)
- 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)
- a significant increase in high blood pressure
- hormonal imbalance

Treatment with Provera Tablets may cause you to have symptoms associated with Cushing's syndrome.

Meningioma
Use of medroxyprogesterone acetate has been linked to the development of a usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma). The risk increases especially when you use it for longer duration (several years). If you are diagnosed with meningioma, your doctor will reconsider your treatment with Provera Tablets. If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

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 Tablets. You are more likely to get a clot whether or not you are taking Provera Tablets 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

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

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

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.
Some drugs may affect the action of Provera Tablets in your body. Tell your doctor or pharmacist if you are taking:
- anticonvulsants like phenobarbital, phenytoin, carbamazepine for epilepsy (fits)
- anti-infective medicines like rifampicin, rifabutin, efavirenz or nevirapine for infections caused by bacteria and yeast
- ritonavir and nelfinavir, sometimes used to treat HIV and AIDS
- cytotoxic drugs (drugs that kill cancerous cells)
- ciclosporin for suppressing the immune system
- herbal preparations containing St. John's wort
- aminoglutethimide sometimes used in Cushing's syndrome
- anticoagulants like warfarin for thinning the blood
- pain killers like aspirin, ibuprofen or naproxen and vasodilators like hydralazine, minoxidil may affect the way Provera Tablets work.

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.

Avoid becoming pregnant while being treated with Provera Tablets. This medicine must not be taken if you are pregnant as hormonal medicines may affect the developing baby. Tell your doctor if you have had an abortion or 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 Tablets.

Breast-feeding
You should stop breast feeding before starting treatment with Provera Tablets as this medicine may be harmful to infants being breast-fed.

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.

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

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

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 Tablets may affect their results.

Provera Tablets contain sodium benzoate and sodium
This medicine contains 0.139 mg (100 mg tablet), 0.278 mg (200 mg tablet), 0.555 mg (400 mg tablet) sodium benzoate in each tablet. Sodium benzoate may increase jaundice

(yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). However, this medicine is normally only used by adults, this warning is only included for completeness.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Cancer of the Endometrium (womb lining) and Kidney:
The usual dose is 200 mg to 600 mg a day.

Breast Cancer:
The usual dose is 400 mg to 1500 mg a day. The chance of having a minor side effect, such as indigestion and weight gain, increases as the dose increases.

Swallow each tablet whole. Take your tablets at the same time each day. Follow your doctors' 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 Tablets than you should
If you take too many Provera tablets, contact your doctor straight away.

If you forget to take Provera Tablets
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 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 some side effects although not everybody gets them.

Reasons for stopping Provera Tablets immediately
If you experience any of the symptoms mentioned below, you should **stop taking** Provera tablets and seek emergency medical help **immediately**.

Uncommon side-effects: may affect up to 1 in 100 people
- increased symptoms of diabetes mellitus (e.g feeling thirsty, passing urine more frequently)
- heart failure (e.g shortness of breath, swelling in legs)
- swelling in the veins due to blood clots

- blood clots, including clots in the lung (e.g pain and swelling in legs, sudden shortness of breath, sudden, severe, sharp pain in your chest, coughing up blood, heart beating more rapidly, any part of your body feeling weak or numb or unable to move)
- raised blood calcium levels (hypercalcaemia)

Rare side-effects: may affect up to 1 in 1,000 people
Your treatment will be discontinued if you have any of the following rare symptoms:
- yellowing of the skin or whites of the eyes or liver problems
- significant increase in blood pressure
- new onset of migraine-type headache
- allergic reaction (wheezing, difficulty breathing, feeling faint, swelling of the face or tongue, swelling of the hands and feet, intense itchy skin rash)
- heart attack (chest pain, tightness or pressure in the chest, shortness of breath)
- stroke (severe or long headache, sight is affected in any way, difficulty speaking, collapse, fainting)
- deep-vein thrombosis (DVT) (pain, tenderness or swelling in your calf, ankle or foot, purple discolouration of the skin of the leg or the skin becomes red and warm to touch)

Not known: frequency cannot be estimated from the available data
- unusual vaginal bleeding
- loss of vision
- sudden onset of enlarged eyeball
- double vision
- migraine
- severe allergic reaction (anaphylactic reaction)
- nettle rash or hives
- meningioma (a usually benign tumour of the tissue surrounding the brain and spinal cord) (see section 2 "Warnings and precautions")
- palpitation

If you get any other side effects reported with Provera tablets these should be discussed with your doctor. Side-effects may include the following:

Common side-effects: may affect up to 1 in 10 people
- impotence
- difficulty sleeping
- tiredness
- dizziness
- tremors
- effects like fine hand tremors
- headache
- vomiting
- constipation
- feeling sick
- weight fluctuation
- change in appetite
- sweating
- fluid retention

Uncommon side-effects: may affect up to 1 in 100 people
- breast pain and tenderness
- unexpected or unusual vaginal bleeding or spotting

- changes in libido (sex drive)
- euphoria (a state of extreme well-being and pleasure)
- depression
- muscular cramps
- diarrhoea
- dry mouth
- acne
- facial hair growth
- Cushingoid syndrome (e.g. puffiness, moon face, weight gain)

Rare side-effects: may affect up to 1 in 1,000 people
- nervousness
- drowsiness
- hair loss
- rash
- decreased sugar tolerance
- fever
- any part of your body feels weak or numb or cannot move

Not known: frequency cannot be estimated from the available data
- stopping or extended break of your periods and vaginal discharge
- milky discharge from the breast when not pregnant or breastfeeding
- confusion
- loss of concentration
- vision disorders
- cloudy vision
- cramps in calves at night
- glucose present in urine
- raised white blood cells and platelets

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 this medicine out of the sight and reach of children.
The unopened bottles should be stored in the original container until ready for use.
- Provera 100 mg Tablets: Store below 25˚C.
- Provera 200 mg Tablets: Store below 25˚C.
- Provera 400 mg Tablets: Store at room temperature (15˚C - 30˚C).

Provera Tablets should not be used after the expiry date printed on the blister or bottle label and carton 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 contain
Each Provera Tablet contains either 100 mg, 200 mg or 400 mg of the active ingredient medroxyprogesterone acetate.
Provera Tablets also contain the following inactive ingredients: microcrystalline cellulose, maize starch, byco C, macrogol 400, sodium starch glycollate, docusate sodium, sodium benzoate (E 211) and magnesium stearate.

See section 2 “Provera Tablets contain sodium benzoate and sodium”.

What Provera Tablets look like and contents of the pack
Provera Tablets are available in the following pack sizes:
Provera 100 mg Tablets: 30, 60 and 100 tablets in blister strips and 100 tablets in bottle.
Provera 200 mg Tablets: 30 and 100 tablets in blister strips and 100 tablets in bottle.
Provera 400 mg Tablets: 30 tablets in blister strips and 60 tablets in bottle.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
UK

Manufacturer:
Pfizer Italia S.r.l.
Località Marino del Tronto
63100 Ascoli Piceno (AP)
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Company Contact Address:
For further information on this medicine, please contact Medical Information at Pfizer Limited in Walton Oaks, Tadworth, Surrey, UK.
Tel.: 01304 616161

This leaflet was last revised in 10/2025.

Ref: PV HD 12_2