PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROVERA® 100

PROVERA® 500

Medroxyprogesterone acetate

Sugar free

Read all of this leaflet carefully before you start taking PROVERA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PROVERA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is used in the treatment of cancer of the lining of the womb, cancer of the kidney(s)
- Breast cancer in postmenopausal women

2. What you need to know before you take PROVERA

Do not take PROVERA:

- if you are hypersensitive (allergic) to medroxyprogesterone acetate or to any of the other ingredients in PROVERA (listed in section 6)
- if you are, or think you may be pregnant
- if you have unexplained vaginal bleeding
- if you have liver problems

Warnings and precautions

Take special care with PROVERA:

- if you experience unexpected vaginal bleeding, please contact your doctor who will investigate further.
- if you have a condition that may be affected by weight gain or fluid retention as PROVERA may cause these conditions to worsen.
- if you have suffered from depression, please tell your doctor and stop treatment if it reoccurs.
- if you suffer from diabetes as PROVERA may decrease your glucose tolerance.
- if there is a sudden partial or complete loss of vision, double vision or migraine you should stop taking PROVERA.
- if you develop inflammation of the veins or blood clots in the veins, PROVERA treatment should be stopped.
- if you suffer from a decreased bone mineral density, long-term use of PROVERA may worsen this.
- if you are using a combined oral hormonal treatment post menopause (menopausal hormone therapy (MHT) with PROVERA, this may increase your risk of getting certain cancers like breast cancer and cancer of the ovaries.
- if you have a history of stroke, heart attack, heart disease or a blood clot in the lungs.
- if you are diagnosed or had a history of meningioma (a usually benign tumour that forms in the layers of tissue that cover your brain and spinal cord)
- if you suffer from dementia.
- if you have or have had breast cancer (unless you have been prescribed PROVERA for breast cancer)

Meningioma

Use of PROVERA 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 health care provider straightaway.

PROVERA may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, contact your doctor for advice.

Before starting treatment, you should undergo a complete medical and family history examination. During treatment, periodic examinations should include blood pressure, breasts, abdomen, pelvic organs and a pap smear.

The results of some laboratory tests can be affected if you are taking PROVERA it is important to tell the health care provider you are taking PROVERA if tests and/or samples are being taken.

Other medicines and PROVERA

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or health care provider if you are taking a medicine called aminoglutethimide (medicine use to treat breast and prostate cancer) as this may affect the way PROVERA works.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PROVERA.

PROVERA is not to be used in women who are pregnant. You should not take PROVERA if you are breastfeeding your baby.

Driving and using machines

The effect of PROVERA on the ability to drive and use machinery has not been evaluated. Side effects of PROVERA that may affect driving and use of machinery are e.g., dizziness, shaking, loss of concentration and visual related disturbances. Contact your doctor or health care provider if you are unsure.

It is not always possible to predict to what extent PROVERA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PROVERA affects them.

3. How to take PROVERA

Do not share medicines prescribed for you with any other person.

Always take PROVERA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

PROVERA is likely to be used in combination with other anti-cancer medicines.

Endometrial and renal cancer

The recommended dose is 200 mg to 600 mg of PROVERA per day.

Breast cancer in postmenopausal women

The recommended dose is 400 mg to 1 200 mg of PROVERA per day.

Your doctor will tell you how long your treatment with PROVERA will last. Do not stop treatment early.

If you have the impression that the effect of PROVERA is too strong or too weak, tell your doctor or pharmacist.

If you take more PROVERA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PROVERA:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

PROVERA can have side effects.

Not all side effects reported for PROVERA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROVERA, please consult your health care provider for advice.

If any of the following happens, stop taking PROVERA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty swallowing or breathing.
- Rash or itching
- Yellowing of the skin and eyes, also called jaundice
- Cerebral infarction (stroke resulting from a blockage in the blood vessels supplying blood to the brain)
- Heart failure, heart attack
- Blood clots in the veins
- Blood clots in the lungs

These are all very serious side effects. If you have them, you may have had a serious reaction to PROVERA.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequently side effects

- Change in weight
- Increased appetite
- Difficulty sleeping
- Headache
- Dizziness
- Tremors
- Vomiting
- Constipation
- Feeling sick (nausea)
- Increased sweating
- Inability to maintain an erection
- Swelling of feet and ankles
- Fluid retention
- Extreme tiredness

Less frequent side effects

- Medicine sensitivity
- Corticosteroid-like effects
- Worsening of diabetes
- Increased calcium levels in the blood
- Depression
- Intense feeling of happiness or excitement
- Change in sex drive
- Nervousness

- Drowsiness/sleepiness
- Inflammation of the veins
- Diarrhoea
- Dry mouth
- Acne
- Excessive hair growth
- Hair loss
- Rash
- Muscle spasms
- Irregular and/or increased/decreased menstrual bleeding, spotting
- Breast pain
- Feeling unwell
- Fever
- Decreased glucose tolerance
- Increased blood pressure

Frequency not known

- Noncancerous tumour of the tissue surrounding the brain and spinal cord
- Delayed ovulation
- Confusion
- Loss of concentration
- Increased heart and/or breathing rate and/or increased sweating
- Blood clot in the eye, blurry vision, impaired vision
- Fast, irregular heartbeat, palpitations
- Itchiness, red/itchy bumps on skin
- Increased glucose levels in urine
- Absence of menstrual period
- Changes to the cervix
- Cervical discharge

- Milk flow from the breasts not as a result of pregnancy or breastfeeding
- Abnormal liver function test
- Increased white blood cell count
- Increased red blood cell count

Other side effects reported during post marketing

- Rounded appearance of the face
- Severe depression with a higher risk of suicidal thoughts/behaviour and suicide
- Loss of fat tissue
- Breast tenderness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA the_Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc,org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROVERA.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store PROVERA

Store all medicines out of reach of children.

Store at room temperature between 15 °C and 30 °C.

Keep in original container to protect from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PROVERA contains

- The active substance is medroxyprogesterone acetate. Each tablet contains 100 mg and 500 mg medroxyprogesterone acetate respectively and sodium benzoate as preservative.
- The other ingredients are corn starch, docusate sodium, gelatine, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate and sodium starch glycollate.

What PROVERA looks like and contents of the pack

PROVERA 100 mg tablets are white, circular, flat, bevelled tablets marked U467 on one side and scored on the reverse.

PROVERA 100 mg tablets are available in blister packs of 100 tablets.

PROVERA 500 mg tablets are white, capsule-shaped tablets embossed Upjohn 717 on one side only.

PROVERA 500 mg tablets are available in blisters of 30 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

12 December 2025

Registration numbers

PROVERA 100 mg tablets: S/21.8.2/1

PROVERA 500 mg tablets: W/21.8.2/462