

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROVERA® 5

PROVERA® 10

Medroxyprogesterone acetate

Contains sugar (lactose monohydrate and sucrose)

PROVERA 5: Each tablet contains 84,2 mg lactose monohydrate and 1,47 mg sucrose.

PROVERA 10: Each tablet contains 110 mg lactose monohydrate and 2,0 mg sucrose.

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

- Irregular menstruation
- Mild to moderate endometriosis (where tissue similar to the lining of the womb is found elsewhere in the body)

- To minimise any side effects as a result of being treated with estrogen
- To alleviate hot flushes related to menopause
- PROVERA may also be used to help diagnose the reason for an absence of the menstrual period

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
- if you have known or suspected breast cancer or cancer of the genitals
- if you have had an abortion
- if you have, or have previously had inflammation of the veins (thrombophlebitis), blood clots or a stroke

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 (e.g. epilepsy, migraine, asthma or problems with your heart or kidneys)
- 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.
- PROVERA may result in the onset of menopause

- if you are using a combined oral hormonal treatment post-menopause 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 suffer from dementia

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 PROVERA, 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 this medicine.

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

Driving and using machines

The effect of PROVERA on the ability to drive and use machinery has not been evaluated. 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.

PROVERA contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take PROVERA

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

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

Irregular periods

The recommended dose is 5 mg to 10 mg of PROVERA for 5 to 10 days.

Treatment should start on the 16th to 21st day of your cycle.

Endometriosis

The recommended dose is 10 mg of PROVERA up to three times a day for 90 days.

Treatment should start on the 1st day of your menstrual cycle.

To minimise the side effects of estrogen in estrogen treated post-menopausal women

The recommended dose is 5 mg to 10 mg of PROVERA per day for at least 10 days.

Treatment should start on the 16th day of a 25 day course of estrogen therapy.

Progestin withdrawal bleeding should occur on the 3rd to 7th day after PROVERA treatment.

Menopause

The recommended dose is 10 mg to 20 mg of PROVERA per day to be taken continuously.

Amenorrhoea (absence of menstrual periods)

The recommended dose is 5 mg to 10 mg of PROVERA per day for 10 days.

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

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:

Frequent side effects:

- Depression
- Difficulty sleeping
- Nervousness
- Headache
- Dizziness
- Feeling sick (nausea)
- Hair loss
- Acne
- Red/itchy bumps on skin
- Itchiness on skin
- Irregular and/or increased/decreased menstrual bleeding, spotting
- Vaginal discharge
- Breast pain or breast tenderness
- Fever
- Tiredness
- Increased weight

Less frequent side effects:

- Excessive hair growth
- Milk flow from the breasts not as a result of pregnancy or breastfeeding
- Swelling of feet and ankles
- Fluid retention

Frequency not known:

- Delayed ovulation
- Drowsiness/sleepiness
- Blood clots in the lungs
- Blood clots in the veins
- Jaundice
- Rash
- Absence of menstrual period
- Changes to the cervix
- Decreased glucose tolerance
- Decreased weight

Other side effects reported with PROVERA include the following:

- Rounded appearance of the face
- Severe depression with a higher risk of suicidal thoughts/behaviour and suicide
- Blood clot in the eye, inflammation of the optic nerve
- Jaundice in the new born
- Change in the colour of the skin
- Loss of fat tissue

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PROVERA.

5. How to store PROVERA

- Store all medicines out of reach of children.
- Store at or below 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 5 mg or 10 mg medroxyprogesterone acetate respectively.
- The other ingredients are calcium stearate, lactose monohydrate, liquid paraffin, maize starch, sucrose and talc. PROVERA 5 mg tablets also contains a colourant (FD & C Blue No. 2 Aluminium Lake colour mixture CI: 73015).

What PROVERA looks like and contents of the pack

PROVERA 5 mg tablets are available in blister packs of 30 and 100 tablets.

PROVERA 5 mg tablets are light blue, round tablets. One surface is engraved with the logo “286” on both sides of the break score. The other surface is engraved with the logo “U”.

PROVERA 10 mg tablets are available in blister packs of 30 and 100 tablets.

PROVERA 10 mg tablets are white, round, semi-oval, convex tablet, scored on one side and marked “Upjohn 50” on the reverse.

Holder of Certificate of Registration

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