

PACKAGE LEAFLET: INFORMATION FOR THE USER

Proviron 25 mg, tablets

(mesterolone)

Read all of this leaflet carefully before you start taking 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 Proviron is and what it is used for
2. What you need to know before you take Proviron
3. How to take Proviron
4. Possible side effects
5. How to store Proviron
6. Contents of the pack and other information

1. WHAT PROVIRON IS AND WHAT IT IS USED FOR

Proviron balances a deficiency in androgen formation that starts to gradually decrease with an increase in age. Therefore, Proviron is suitable for the treatment of all conditions caused by the deficient formation of endogenous androgens.

Disorders due to androgen deficiency:

Decreased physical activity, rapid fatigability, decreased memory and concentration, libido and potency disturbances, irritability, insomnia, tendency to depression, vegetative disturbances in general. All these states of insufficiency can be the consequence of an androgenic deficit and disappear or improve through treatment with Proviron.

Proviron suppresses potency disturbances due to androgen deficiency. When other isolated or coadjutant etiological factors exist, Proviron may be prescribed as additional medication.

Hypogonadism:

Proviron stimulates the growth, development and function of effector organs under androgenic influence, as well as the development of secondary male sexual characteristics in cases of pre-pubertal androgen insufficiency.

Proviron eliminates the symptoms after puberty originated by the loss of sexual gland function.

Infertility:

Both oligospermia and Leydig cell insufficiency may be the cause of infertility. Proviron increases the number of spermatozoa and improves their quality by raising and normalizing fructose concentration in the ejaculate. All of this contributes to increase fertilization possibilities.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROVIRON

Do not take Proviron:

- if you are allergic to mesterolone or any of the other ingredients of Proviron (indicated in section 6).
- if you have prostate cancer.
- if you have or have had a hepatic tumour.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Proviron.
Proviron is only intended for use in male patients.

Drug abuse and dependency:

Always take Proviron exactly as your doctor or pharmacist has told you.
You should not use Proviron to for muscle development, increase muscle mass in healthy men or to increase another physical capacity, be it on its own or with other anabolic-androgenic steroids, because it carries serious health risks, such as problems with your heart and blood vessel (that can result in death), liver and/or mental health, or you could become dependent on these drugs.

Contact your doctor immediately in case of frequent or long-lasting erections, as it can damage you penis. Your doctor will advise you better.

When you are taking Proviron, your doctor will carry out regular tests.

Tell your doctor in the event of unusual and long-term complaints in the upper part of the stomach, because this could be a life-threatening stomach haemorrhage.

Other medicines and Proviron:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and fertility:

Proviron must not be taken by women.

If you take it, as recommended, Proviron will not damage your spermatozoa.

It can even increase the number and quality of your sperm and, therefore, increase your chances of becoming a father.

Driving and using machines:

Proviron has no observed effects on your ability to drive or use machines.

Proviron contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact him before taking this product.

3. HOW TO TAKE PROVIRON

Always take Proviron exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you have any doubts.

The tablets must be taken whole with the amount of liquid needed.

Unless otherwise prescribed, the following dosing schedule is recommended:

Disturbances due to androgen deficiency:

Start:

1 tablet of Proviron 3 times a day.

When a satisfactory improvement has been achieved, a dose reduction can be attempted.

Maintenance:

1 tablet of Proviron twice a day.

Depending on the nature and intensity of the disturbance or symptoms, this maintenance dose should be adapted to individual needs. Continuous treatment is recommended for several months.

Hypogonadism requires prolonged treatment:

Start: To stimulate the development of secondary male sexual characteristics it is necessary to administer 1-2 Proviron tablets 3 times a day for several months.

Maintenance: As a maintenance dose a Proviron tablet 2-3 times per day may be sufficient.

Infertility - to increase sperm count and improve its quality:

One Proviron tablet 2-3 times per day over a complete spermatogenic cycle, approximately 90 days. Sometimes it is convenient to repeat the treatment after an interval of several weeks.

To increase the concentration of fructose in ejaculate in cases of insufficiency of Leydig cells after puberty it is recommended to administer a Proviron tablet twice daily for several months.

If you take more Proviron than you should:

There are no reports of serious harmful effects resulting from ingestion of too many Proviron tablets at the same time. Always take Proviron exactly as your doctor indicated. If you took more tablets than you should, contact your doctor or pharmacist immediately.

Check with your doctor or pharmacist if you are not sure.

If you forget to take Proviron:

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Proviron can cause side effects, although not everybody gets them.

Not known: frequency cannot be estimated from the available data

- Abdominal pains (stomach discomfort)
- Acne
- Alopecia (hair loss)
- Headache
- Frequent penis erections
- Priapism (prolonged and undesirable penis erections)

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):	
Jordan: Tel: +962-6-5632000 JFDA email : jpc@jfda.jo JFDA website: www.jfda.jo http://primaryreporting.who-umc.org/JO	Egypt: Egyptian Pharmaceutical Vigilance Centre Hotline: 15301 Email: pv.followup@edaegypt.gov.eg Website: www.edaegypt.gov.eg
United Arab Emirates (UAE): Pharmacovigilance & Medical Device section Tel: 800111111 / +971 42301000 Email: pv@mohap.gov.ae Website: www.mohap.gov.ae P.O.Box 1853 Dubai	Oman: Tel: +968 - 2444 1999 Fax: +968 - 24602287 Email: pharma-vigil@moh.gov.om Website: www.moh.gov.om
Kuwait: Drug & Food Control, Ministry of Health Tel.: +965-24811532 Fax: +965-24811507 Email : Adr_reporting@moh.gov.kw Website: http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx	Other Countries: Please contact the relevant competent authority

5. HOW TO STORE PROVIRON

Do not store above 30 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after the abbreviation for expiry date 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 to protect the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What Proviron contains:

- The active substance is mesterolone.
- The other ingredients are lactose monohydrate, corn starch, povidone 25000, methyl hydroxybenzoate, propyl hydroxybenzoate and magnesium stearate.

What Proviron looks like and contents of the pack:

Packing with 20 tablets, dosed at 25 mg

Manufacturer:

Bayer Weimar GmbH & Co KG
99427 – Weimar, Germany

Marketing authorization holder:

Bayer AG,
Leverkusen, Germany.

This leaflet was last approved in November 2023

This is a medicament.

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

**Council of Arab Health Ministers
Union of Arab Pharmacist**