

PACKAGE LEAFLET: INFORMATION FOR THE USER

Proviron 25mg - Tablets

Mesterolone

Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Proviron is and what it is used for
2. Before you take Proviron
3. How to take Proviron
4. Possible side effects
5. How to store Proviron
6. Further information

1. What Proviron is and what it is used for

What is Proviron?

Proviron is a medicine containing mesterolone. It is a form of androgen (male hormone) therapy.

What is Proviron used for?

Proviron is used in men who do not naturally produce enough androgens (male hormones).

It is also used in men who are infertile due to low levels of male hormones (caused by hypogonadism, inadequate functioning of the testes).

2. Before you take Proviron

Do not take Proviron if:

- you are allergic (hypersensitive) to mesterolone or any of the other ingredients of Proviron (see Section 6: Further Information)
- you have prostate cancer
- you have (or have had) a liver tumour.

Take special care with Proviron:

- You will have regular examinations of the prostate while taking Proviron to rule out the possibility of prostate cancer. This is because Proviron may increase the growth rate of this type of cancer.
- Using hormones, such as the one in Proviron, has rarely been linked to benign (non-malignant) liver tumours. Very rarely, using hormones has been associated with some forms of liver cancer (malignant liver tumours). Liver tumours may lead to bleeding in the abdomen, which can be life-threatening. **If you have any new "stomach" discomfort or pain that does not go away quickly, you must tell your doctor straight away.**
- Proviron is not suitable for body-building, increasing muscles in healthy men or for increasing other physical ability.
- Proviron should be taken by men only.

Taking or using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Driving and using machines

Taking Proviron is not thought to have any effect on driving or using machines.

Important information about some of the ingredients in Proviron

- If you have been told by your doctor that you cannot tolerate or digest some sugars, tell your doctor before you start taking Proviron. This is because it contains lactose (a type of sugar).
- Proviron contains methyl and propyl parabens which may cause allergic reactions (possibly delayed).

3. How to take Proviron

Always take Proviron exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

- The usual amount is one tablet, taken 3 or 4 times a day.
- Swallow the tablet whole with a drink of water. After you have taken Proviron for a few months, your doctor may decide to reduce the number of tablets you need to take each day.

If you take more Proviron than you should

Talk to your doctor who will tell you what you need to do. There have been no reports of serious illness from taking too much Proviron.

If you forget to take Proviron

Do not take a double dose to make up for a forgotten tablet. When you remember, take the next dose and continue with the tablets as normal.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

- **Discomfort or pain in your “stomach” (abdomen)** If you get pain or discomfort in your “stomach” or abdomen that does not go away quickly, tell your doctor straight away. (See Section 2: Before you take Proviron).
- **Frequent erections or erections that do not go away** If you get unusually frequent erections or erections that do not easily go away, tell your doctor. Your doctor may ask you to stop taking Proviron in order to avoid injury to your penis.

Talk to your doctor if you notice any change in your health or general sense of well-being when taking Proviron. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Proviron

- Keep out of the reach and sight of children.
- Store below 30°C.
- Do not use Proviron after the expiry date which is stated on the box after the letters ‘EXP’. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Proviron contains

- The active substance is mesterolone. Each tablet contains 25mg of mesterolone.
- The other ingredients are lactose, maize starch, povidone (E1201), methylparaben (E218), propylparaben (E216) and magnesium stearate (E572).

What Proviron looks like and contents of the pack

Each pack of Proviron contains 1 strip of 20 white tablets.

Manufacturer:

Bayer Weimar GmbH & Co KG
99427 – Weimar, Germany

Marketing Authorization Holder:

Bayer AG,
Kaiser-Wilhelm-Allee 1
51373 Leverkusen, Germany

This leaflet was revised on: 1st May 2008

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 Pharmacists