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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

PACKAGE LEAFLET: INFORMATION FOR THE USER**PRO-VIRON® 25mg tablet**

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 Pro-Viron is and what it is used for
2. Before you take Pro-Viron
3. How to take Pro-Viron
4. Possible side effects
5. How to store Pro-Viron
6. Further information

1. What Pro-Viron is and what it is used for**What is Pro-Viron?**

Pro-Viron is a medicine containing mesterolone. It is a form of androgen (male hormone) therapy.

What is Pro-Viron used for?

- Pro-Viron 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 Pro-Viron**Do not take Pro-Viron if:**

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

Take special care with Pro-Viron:

- You will have regular examinations of the prostate while taking Pro-Viron to rule out the possibility of prostate cancer. This is because Pro-Viron may increase the growth rate of this type of cancer.
- Using hormones, such as the one in Pro-Viron, 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.**
- Pro-Viron is not suitable for body-building, increasing muscles in healthy men or for increasing other physical ability.
- Pro-Viron 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 Pro-Viron is not thought to have any effect on driving or using machines.

Important information about some of the ingredients in Pro-Viron

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

3. How to take Pro-Viron

Always take Pro-Viron 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 Pro-Viron for a few months, your doctor may decide to reduce the number of tablets you need to take each day.

If you take more Pro-Viron 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 Pro-Viron.

If you forget to take Pro-Viron

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, Pro-Viron 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 Pro-Viron).
- **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 Pro-Viron 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 Pro-Viron.

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 Pro-Viron

- Keep out of the reach and sight of children.
- Do not use Pro-Viron 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 Pro-Viron 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 Pro-Viron looks like and contents of the pack

Each pack of Pro-Viron contains 3 strips of 10 white tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bayer plc
Bayer House
Strawberry Hill
Newbury
Berkshire RG14 1JA
United Kingdom

Manufacturer:

Bayer Pharma AG
Berlin
Germany
or
Bayer Weimar GmbH &Co KG
Weimar
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