

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Proviron.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Proviron against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT PROVIRON IS USED FOR

Proviron is used to replace testosterone in men with hypogonadism. Male hypogonadism is a condition when the body does not produce enough testosterone.

Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development in men.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

Proviron is for use in male patients only.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU USE PROVIRON

When you must not take it

Do not take Proviron if you have an allergy to:

- mesterolone, the active ingredient in Proviron
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Proviron if you have:

- prostate cancer
- previous or existing liver tumours
- male breast cancer
- high blood calcium levels

Do not use this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before starting Proviron, your doctor will conduct an examination of your prostate. Your doctor will also note your medical history and perform other tests including a blood test.

Tell your doctor if you have or have had any of the following medical conditions:

- prostate disease
- liver disease
- heart or blood vessel disease
- high blood pressure
- kidney disease
- difficulty passing urine
- migraines
- epilepsy
- diabetes
- sleep apnoea (abnormal pauses in breathing during sleep)
- polycythaemia (a blood disorder where too many red blood cells are being produced)
- porphyria a rare metabolising disorder

If you have not told your doctor about any of the above, tell him/her before you start taking Proviron.

Use of androgens for reasons other than what your doctor prescribed carries a serious health risk and is strongly discouraged.

Use of Proviron during puberty can stunt your growth. Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Proviron may interfere with each other. These include:

- phenobarbital or phenytoin, medicines used to treat seizures
- cyclosporin, a medicine used to suppress the immune system
- medicines used for diabetes
- thyroxine, a medicine used to replace low thyroid levels
- oral anticoagulants such as warfarin, 'blood thinning' medications to treat or prevent blood clots
- neuromuscular blockers such as anaesthetics, medicines used to cause temporary paralysis

These medicines may be affected by Proviron or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE PROVIRON

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much and how often you should take Proviron.

For Proviron to work best it is very important to take it exactly as your doctor tells you.

The usual treatment consists of 1-2 tablets three times per day. After a few months of treatment, your doctor may decrease the dose to 1 tablet two to three times a day.

Do not exceed the recommended dose your doctor has prescribed for you as this can increase your risk of side effects.

How to take it

Swallow the tablet whole with water.

When to take it

Take your medicine at about the same time each day

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have taken too much Proviron. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Excessive use of hormonal substances such as Proviron has been associated with liver abnormalities, tumours, changes to blood lipids, increased risk of heart disease, reduced glucose tolerance, decreased testosterone levels, enlargement of male breast tissue, stunted growth, psychiatric disturbances, acute withdrawal syndrome, vomiting blood or blood in stools and tendon damage.

WHILE YOU ARE TAKING PROVIRON

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Proviron.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as blood tests and regular examinations of the prostate) from time to time to make sure the medicine is working and to check for unwanted side effects.

If you experience prolonged stomach pain, blood in the stools or vomit, or yellowing of the skins and eyes during treatment with Proviron, tell your doctor immediately

There have been cases reported of patients developing liver tumours while taking Proviron. Your doctor may tell you to stop using Proviron.

Things you must not do

Do not take Proviron to treat any other complaints unless your doctor tells you to.

Do not give your Proviron tablets to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Proviron.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- fluid retention
- breast enlargement
- increased sexual drive
- psychiatric disturbances such as depression, aggression, increased or decreased energy levels, elation or irritability
- acne
- excessive hairiness
- premature puberty
- stunted growth

Tell your doctor immediately, or go to Accident and Emergency department at your nearest hospital if you notice any of the following:

- symptoms of an enlarged prostate such as changes in urination, or blood in the urine or ejaculate

- unwanted, frequent or prolonged and painful erections
- severe stomach pain or tenderness which do not disappear within a short time

You may need urgent medical attention or hospitalisation.

Hormonal substances such as Proviron may quicken the growth of existing hormone dependent tissues and tumours. If you are over 65 years of age, you may have an increased risk of developing prostatic hyperplasia (enlargement of the prostate) and prostatic cancer.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING PROVIRON

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Proviron or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Proviron tablets are round white scored tablets marked with "AX" inside a hexagon.

Each pack contains 50 tablets.

Ingredients

Active ingredient:

- 25 mg mesterolone per tablet

Inactive ingredients:

- lactose
- maize starch
- povidone
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- magnesium stearate

Supplier

Made in Germany for:

Bayer Australia Ltd

ABN 22 000 138 714

875 Pacific Highway

Pymble NSW 2073

Australian Registration Number

Proviron (blister pack) - AUST R 136196

Proviron (bottle) - AUST R 10712

Date of preparation

November 2012

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

® Registered trademark of the Bayer Group, Germany

© Bayer Australia Ltd

All rights reserved

