

Anterone 50 Tablets

Cyproterone acetate 50mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Anterone 50 tablets. It does not contain all 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 Anterone 50 tablets against the benefits the medicine is expected to 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.

1. What Anterone 50 tablets are used for

Anterone 50 tablets are an antiandrogenic hormone medication containing the active ingredient cyproterone acetate, which is used to treat cancer of the prostate gland.

It can also be used in conjunction with other medications or following surgical removal of the testes to treat side effects such as "sweats" or "hot flushes" and to prevent any initial worsening of the disease.

Androgenic hormones are generally required for cancer of the prostate gland to grow. Anterone 50 tablets work in two ways.

Firstly they stop the androgenic hormones (testosterone) present in your body from being able to attach to the cancer cells.

Secondly they decrease the amount of androgen hormone present in your blood stream by an effect on the hormonal mechanisms that control androgen production by the body, Anterone 50 tablets can be used to reduce the sex drive of men with sexual deviations.

It is also used in the treatment of women who have a problem with facial or chest hair, are balding or have severe acne.

Anterone 50 tablets are only available on a doctor's prescription.

There is no evidence that Anterone 50 tablets are addictive.

2. Before you take Anterone 50 tablets

Anterone 50 tablets can rarely cause severe damage to your liver, resulting in jaundice and hepatitis.

Your doctor should perform a blood test to check your liver before starting you on Anterone 50 tablets and again if liver disease is suspected.

Yellowing of the skin/eyes, darkening of the urine and abdominal pain or swelling should be all reported immediately to your doctor.

As with other sex steroids, benign and malignant liver changes have been reported in isolated cases.

In very rare cases, liver tumours may lead to life-threatening bleeding into the stomach. You must inform your doctor of the occurrence of unusual upper abdominal complaints which do not

disappear spontaneously within a short time.

Anterone 50 tablets have been observed to attach itself to the genetic material in animal and human liver cells. It would appear, however, that this does not lead to an increase in liver cancer. Female patients should be aware that the long term effects of Anterone 50 tablets on fertility are not known. A doctor should carry out a thorough gynaecological examination before starting treatment.

Anterone 50 tablets cause a decrease in sperm count. It may take between 3 to 20 months for the sperm count to return to normal once therapy has been stopped. Male patients may need to have a sperm count.

3. Using Anterone 50

Tell your doctor if:

- You are pregnant or breastfeeding, " You have a history of herpes of pregnancy.
- You suffer from or have a history of jaundice or persistent itching during a previous pregnancy.
Anterone 50 tablets should not be taken during pregnancy as it may lead to the development of female characteristics in male babies.
- You have in the past suffered from blood clots in the leg, stroke or heart attack.
- You are allergic to any other medicines or other substances such as foods, dyes or

preservatives or any of the ingredients in the tablet.

- You have severe diabetes that has damaged your blood vessels.
- You have sickle-cell anaemia.
- You have suffered from any disease or tumour of your liver
- You have suffered from severe chronic depression.
- You have Dubin-Johnson syndrome or Rotor syndrome.

If you are not sure whether you should be taking Anterone 50 tablets, talk to your doctor.

Do not take Anterone 50 tablets if:

- The expiry date on the pack has passed. If you take this medicine after the date has passed it may have no effect at all, or worse, an entirely unexpected effect.
- The packaging is torn or shows signs of tampering or if the tablets do not look quite right. Do not give Anterone 50 tablets to children.

Taking other medicines

Tell your doctor if you are taking any other medicines. Some medicines interfere with Anterone 50 tablets. These include:

- Penicillins (antibiotic).
- Rifampicin (antibiotic).
- Anticonvulsants, medicines used to treat fits.

These medicines may be affected by Anterone 50 tablets or may affect how well your medicine works. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Anterone 50 tablets

4. How to take Anterone 50 tablets

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack: ask your doctor or pharmacist for help. The dosage of Anterone 50 tablets will be determined by your doctor. The usual dose ranges from one tablet once daily, to one tablet two or three times a day. The tablet should be taken with some liquid after meals.

If you forget to take it

If it is almost time to take your next dose, skip the dose that you have missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, then go back to taking your tablets as usual. Do not double a dose to make up for a dose that you have missed.

5. If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia and 0800 POISON (764766) in New Zealand) for advice, or go to the casualty department at your nearest hospital, if you think that you or anyone else may have taken too many Anterone 50 tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

6. While you are taking Anterone 50 tablets

Things you must do

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Anterone 50 tablets. You may be required to have regular tests for liver, blood or other body functions.

Female patients who have a family history of breast cancer and are taking the combined Anterone 50 /ethinyloestradiol treatment should have regular breast examinations.

Things you must not do

Do not use Anterone 50 tablets to treat any other medical complaints unless your doctor tells you to.

Do not give Anterone 50 tablets to anyone else, even if they have the same condition as you.

Things to be careful of

Anterone 50 tablets may cause drowsiness and loss of concentration in some people. Be careful driving or operating machinery until you know how Anterone 50 tablets affect you.

Female patients should not smoke whilst taking combined Anterone 50/ethinyloestradiol treatment.

Use of any oral contraceptives may be associated with an increased risk of stroke and heart attack.

Female patients should be aware that the contraceptive action of the combined treatment of Anterone 50 tablets and ethinyloestradiol may be reduced by diarrhoea or vomiting shortly after taking a tablet. In these cases, an additional form of contraception such as a diaphragm or condom should be used for the remainder of the cycle.

In women taking combined Anterone 50 /ethinyloestradiol treatment, if light bleeding or spotting occurs during the 3 weeks in which the tablets are being taken, do not stop taking your tablets. However, if bleeding is heavy, consult your doctor immediately. If you are taking Anterone 50 tablets to reduce your sex drive, alcohol may stop Anterone 50 tablets from working as well as it should.

7. Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking Anterone 50 tablets, even if you do not think that the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Anterone 50 tablets can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have. Infertility and impotence are expected effects of Anterone 50 tablets and cannot generally be avoided. The most common side effect that may occur is tiredness and loss of concentration which may affect your ability to drive or operate machinery.

Anterone 50 tablets may occasionally result in gynaecomastia (swelling of the breast area which is sometimes also associated with tenderness or sensitivity of the breast area to touch), diminished libido, changes in body weight, nausea, allergy, depressive moods, headache, shortness of breath and blood clotting (which may lead to a clot on the lungs, stroke or heart attack). This is not a complete list of all possible side effects.

Tell your doctor if you notice any other effects while using Anterone 50 tablets.

8. After using Anterone 50 tablets

Storage

Keep your tablets in the blister in the tablet pack carton until it is time to take them. If you take the tablets out of the blister they may not keep as well.

Keep Anterone 50 tablets in a cool dry place where the temperature stays below 25 degrees Celcius. Do not store Anterone 50 tablets or any other medicine in the bathroom or near a sink. Do not leave Anterone 50 tablets in the car or on window sills as heat and dampness can destroy some medicines. Keep Anterone 50 tablets where children cannot reach them. A locked at least on-and-a-half metres above the ground is a good place to store medicines.

Disposal

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

9. Product Description

9a) What Anterone 50 tablets are

Anterone 50 is the brand name for white tablets containing 50 milligrams of the antiandrogenic substance, cyproterone acetate.

Anterone 50 tablets are presented in blister packs containing 20 and 50 tablets.

Each Anterone 50 tablet pack is identified by an Australian Registration Number and this appears on the pack (AUST R 278777).

9b) Ingredients

Each Anterone 50 tablet contains cyproterone acetate 50mg as the active ingredient.

As well as its active ingredient, Anterone 50 tablets contain lactose monohydrate, starch-maize, povidone, magnesium stearate, silica-colloidal anhydrous and starch-pregelatinised maize.

9c) Sponsor

Cipla Australia Pty Ltd
Level 1, 132 – 136 Albert Road
South Melbourne VIC 3205

This leaflet was prepared in
September 2016