

Anterone 100

Cyproterone acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Anterone 100 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 100 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.

What Anterone 100 is used for

Anterone 100 tablets contain cyproterone acetate as the active ingredient. Cyproterone acetate belongs to a group of medicines called anti-androgens. It blocks the action of male sex hormones (androgens) which are released naturally in the body. It also reduces the production of androgens.

It has been shown that the growth of tumours of the prostate gland may be dependent on male hormones. Since cyproterone acetate blocks the action of androgens and reduces the amount of androgens produced by the body, it can be used to help treat cancer of the prostate gland. It can also be used in conjunction with

other medications 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.

Anterone 100 is for use only in men.

This medicine is available only with a doctor's prescription.

There is no evidence that Anterone 100 tablets are addictive.

Before you take it

When you must not take it

Do not take Anterone 100 if you are allergic to:

- cyproterone acetate
- any other ingredients listed at the end of this leaflet.

Do not take Anterone 100 if you suffer from:

- liver disease, previous or existing liver tumours unless they are caused by metastases from prostate cancer (your doctor would have told you if you have this)
- existing blood clots
- previous or existing benign brain tumour (meningioma)
- severe chronic depression
- Dubin-Johnson syndrome or Rotor syndrome (your doctor would have told you if you have either of these conditions)
- wasting diseases (with the exception of cancer of the prostate)
- a rare hereditary problem associated with lactose

monohydrate e.g. galactose intolerance and Lapp lactase deficiency.

Do not take Anterone 100 if you are under 18 years of age.

It is not recommended for use in male children and adolescents below 18 years of age as the safety and effectiveness in this age group has not been established.

Do not take Anterone 100 after the expiry date printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take it if the packaging shows signs of tampering or the tablets do not look quite right.

Talk to your doctor if you are not sure whether you start taking this medicine.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- diabetes
- history of blood clotting or sickle cell anaemia
- osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines)

Tell your doctor if fertility after treatment is important.

In this case it is advisable to have a spermatogram before taking Cyprocur 100 to establish your

fertility before commencing therapy. It can take 3-20 months for fertile sperm production to be re-established after stopping this medicine.

If you have not told your doctor about any of the above, tell them before you start taking Anterone 100.

Taking other medicines

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

Some medicines reduce the contraceptive effectiveness of Anterone 100.

These include:

- phenytoin, a medicine used to treat epilepsy
- medicines used to treat fungal infections, including ketoconazole, itraconazole, clotrimazole
- ritonavir, a medicine used in the treatment of HIV
- rifampicin, a bactericidal antibiotic used to treat infections such as tuberculosis and leprosy
- St John's wort, a herbal remedy used to treat mood disorders
- statins (HMGCoA inhibitors), medicines used to lower cholesterol levels in people with or at risk of cardiovascular disease
- medicines used to treat diabetes.

These medicines may be affected by Anterone 100 or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Anterone 100.

How to take it

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you the dose that you should take and whether your need to take it with other medicines.

The usual daily dose is 50-300 mg (one half to three tablets) of Anterone 100.

Do not alter the dose yourself.

Your doctor will advise you if changing the dose is necessary.

How to take it

Swallow the tablets with some liquid after meals.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to 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 your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for

advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too many Anterone 100 tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Anterone 100, especially if you are starting any new medicines.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Your doctor will check your liver function during treatment with Anterone 100 and whenever any signs or symptoms suggesting liver problems are observed.

If you have diabetes, your doctor will monitor you to ensure that you receive the appropriate dose of oral antidiabetic or insulin.

Your doctor will also check your red blood cell count to ensure you do not become anaemic during treatment with this medicine.

Things you must not do

Do not take Anterone 100 to treat any other complaints unless your doctor tells you to.

Do not give your medicine 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.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Anterone 100 may cause drowsiness and loss of concentration in some people

Side effects

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

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

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

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

- tiredness
- weight increase
- decreased sexual drive
- headache
- depressive mood
- fast heart beat
- nausea and other gastrointestinal complaints
- breast pain, change in breast size, breast swelling and/or tenderness
- osteoporosis
- hot flushes, sweating.

These side effects are common.

If you were fertile before treatment, Anterone 100 may also result in your inability to produce sperm (infertility). Fertility is usually regained within a few months of discontinuing therapy.

Anterone 100 may also result in the inability to get or maintain an erection (impotence). This ability is usually also regained within a few months of discontinuing therapy.

Tell your doctor as soon as possible if you notice any of the following side effects:

- yellowing of the skin and/or eyes
- severe upper abdominal pain.

These serious side effects are rare and may require medical attention.

If the following happens, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling.

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

Other side effects not listed above may happen in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in a cool dry place, protected from light, where the temperature stays below 25 °C.

Keep the tablets in the foil blister until it is time to take them.

If you take the tablets out of the foil blister, they may not keep as well.

Do not store Anterone 100 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach them.

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 Anterone 100 or your

tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

Anterone 100 are white, capsule shaped, biconvex tablets with 'CPA 100' marked on one side and scored on the other.

Available in packs of 20 and 50 tablets.

Ingredients

Active ingredient:

Each Anterone 100 tablet contains 100 mg of cyproterone acetate.

Each Anterone 100 tablet pack is identified by an Australian Registration Number and this appears on the pack (AUST R 278778).

Inactive ingredients:

- lactose monohydrate
- starch-maize
- starch-pregelatinised maize
- povidone
- magnesium stearate
- silica-colloidal anhydrous.

Anterone 100 tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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