Anterone 100

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Anterone 100?

Anterone 100 contains the active ingredient cyproterone acetate. Anterone 100 may slow or stop the growth of cancer. Anterone 100 tablets may be used in combination with other medicines or following surgical removal of the testes to treat side effects such as “hot flushes” or “sweats” and to prevent any initial worsening of the disease.

For more information, see Section 1. Why am I using Anterone 100? in the full CMI.

2. What should I know before I use Anterone 100?

Do not use if you have ever had an allergic reaction to cyproterone acetate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Anterone 100? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Anterone 100 and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Anterone 100?

The usual daily dose is 50-300 mg of Anterone 100. Your doctor may request you take Anterone 100 with other medicines and/or change your dose during treatment.

Your doctor will advise of the most suitable dose for you to take. Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section 4. How do I use Anterone 100? in the full CMI.

5. What should I know while using Anterone 100?

Things you should do	• Remind any doctor, dentist or pharmacist when you visit that you are using Anterone 100. • Your doctor may do liver function tests and red-blood cell count to make sure the medicine is working and to prevent unwanted side effects.. • Tell your doctor if you have diabetes
Things you should not do	• Do not stop taking your medicine or lower the dosage without checking with your doctor. • Do not take Anterone-100 to treat any other complaints unless your doctor tells you to
Driving or using machines	• Be careful driving or operating machinery until you know how Anterone 100 affects you. This medicine may cause tiredness and can impair the ability to concentrate.
Drinking alcohol	• Be careful when drinking alcohol while you are taking this medicine. • If you drink alcohol, tiredness and the ability to concentrate may be worse. • Alcohol may prevent Anterone 100 from working as well as it should in reducing abnormal sex drive.
Looking after your medicine	• Keep your tablets in a cool dry place, protected from light, where the temperature stays below 25 °C.

For more information, see Section 5. What should I know while using Anterone 100? in the full CMI.

6. Are there any side effects?

Serious side effects include yellowing of the skin and/or eyes, light coloured bowel motions, dark coloured urine, severe upper abdominal pain, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea, sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs, hearing loss, memory loss, seizures and weakness in the arms or legs.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Anterone 100

Active ingredient(s): *Cyproterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Anterone 100. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Anterone 100.**

Where to find information in this leaflet:

1. Why am I using Anterone 100?
2. What should I know before I use Anterone 100?
3. What if I am taking other medicines?
4. How do I take Anterone 100?
5. What should I know while taking Anterone 100?
6. Are there any side effects?
7. Product details

1. Why am I using Anterone 100?

Anterone 100 contains the active ingredient cyproterone acetate. Anterone 100 tablets are an antiandrogen medicine. It works by blocking the effect of androgens such as testosterone which are natural male sex hormones. Androgens may help the cancer cells to grow in some types of prostate cancer. By blocking these hormones, **Anterone-100 may slow or stop the growth of cancer**

Anterone 100 tablets may be used in combination with other medicines or following surgical removal of the testes to treat side effects such as "hot flushes" or "sweats" and to prevent any initial worsening of the disease.

2. What should I know before I take Anterone 100?

Warnings

Do not use Anterone 100 if:

- you are allergic to cyproterone acetate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- Do not take Anterone 100 if you have any of the following medical conditions:
  - 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)
  - Dubin-Johnson syndrome or Rotor syndrome (your doctor would have told you if you have either of these conditions).
  - previous or existing benign brain tumour (meningioma).
  - wasting disease (a disease causing muscle loss or loss of strength, with the exception of prostate cancer).
  - severe and persistent depression
  - previous or existing conditions relating to formation of blood clots.

Check with your doctor if you:

- Have, or have had any other 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)
- take any medicines for any condition
- have an intolerance to some sugars, Anterone 100 tablets contains lactose monohydrate
- have any allergies to any other medicines, foods, preservative or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Anterone 100 is only for use in men.

Tell your doctor if fertility after treatment is important

• For men it is recommended that a sperm count is taken to establish fertility before commencing Anterone 100. It can take 3-20 months for fertile sperm production to be re-established after stopping this medicine.

Anterone 100 should only be taken by men. It should not be taken by women or children and adolescents below 18 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with Anterone 100 and affect how it works.

- 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, an 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Anterone 100.

4. How do I take Anterone 100?

How much to take

- Follow the instructions provided and take Anterone 100 until your doctor tells you to stop.
- The usual dose is 50-300 mg of Anterone 100. Your doctor may request you take Anterone 100 with other medicines and/or change your dose during treatment.
- Do not alter the dose yourself.
- Your doctor will advise you if changing the dose is necessary.
- Shortness of breath may occur at high doses.

When to take Anterone 100

- Anterone 100 should be taken whole, with some liquid after meals.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Anterone 100 helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Missed Anterone 100 tablets may diminish the effectiveness of treatment.

If you forget to use Anterone 100

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

If you take too much Anterone 100

If you think that you have used too much Anterone 100, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Anterone 100?

Things you should do

- 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 symptoms or signs 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 whilst taking Anterone 100.
- Your doctor will also check your red-blood cell count to ensure you do not become anaemic during treatment with Anterone 100.

Remind any doctor, dentist or pharmacist when you visit that you are using Anterone 100.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Anterone 100 affects you.

Anterone 100 may cause tiredness and can impair the ability to concentrate. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, tiredness and the ability to concentrate may be worse.

The effectiveness of Anterone 100 to reduce abnormal sex drive can also be diminished under the influence of alcohol. Alcohol may prevent Anterone 100 from working as well as it should in reducing abnormal sex drive.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Return any unused medicine to your pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you were fertile before treatment, Anterone 100 will normally prevent sperm production. Fertility is usually regained within a few months of discontinuing therapy.

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

Less serious side effects

Less serious side effects	What to do
• tiredness, fatigue • weight change • headache • depressive mood • nausea and other gastrointestinal complaints • decreased sexual drive • breast pain, change in breast size, breast swelling and/or tenderness • breast enlargement in men • hot flushes, sweating. • shortness of breath • osteoporosis	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• yellowing of the skin and/or eyes, light coloured bowel motions, dark coloured urine • severe upper abdominal pain. • vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea • sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Use of cyproterone acetate has been linked to the development of meningioma (generally benign tumour). The risk increases when used for several years, or with high doses (25 mg per day and above).

Serious side effects	What to do
• changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, • headaches that worsen with time, memory loss, seizures, • weakness in your arms or legs	**Call your doctor straight away, if you notice any of these serious side effects.**

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Anterone100 contains

Active ingredient (main ingredient)	Cyproterone acetate.
Other ingredients (inactive ingredients)	Lactose monohydrate Starch maize Povidone Starch-pregelatinised maize Magnesium stearate, Silica-colloidal anhydrous.

Do not take this medicine if you are allergic to any of these ingredients.

What Anterone 100 looks like
Anterone 100 are white, capsule shaped, biconvex tablets with 'CPA 100' marked on one side and scored on the other. (Aust R 278778).
Available in packs of 20 and 50 tablets.

Who distributes Anterone 100
Cipla Australia Pty Ltd
Level 1, 132 – 136 Albert Road South Melbourne VIC 3205 Email: drugsafety@cipla.com Phone no: 1 800 569 074

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