

Cyprone 100

contains cyproterone acetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Cyprone 100.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Cyprone 100 against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

WHAT CYPRONE 100 IS USED FOR

Cyprone 100 contains cyproterone acetate as the active ingredient.

Cyproterone acetate belongs to a group of medicines called anti-androgens. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow. By blocking these hormones, 100 may slow or stop the growth of cancer.

Cyprone 100 may be used in combination 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.

Cyprone 100 is for use only in men.

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

There is no evidence that Cyprone 100 is addictive.

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 TAKE CYPRONE 100

When you must not take it

Do not take Cyprone 100 if you have an allergy to:

- cyproterone acetate
- 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 Cyprone 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 conditions relating to formation of 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 e.g. galactose intolerance and Lapp lactase deficiency.

Cyprone 100 should not be taken by women or children and adolescents below 18 years of age.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or 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.

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

- 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 (sperm count) before taking Cyprone 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 him/her before you start taking Cyprone 100.

Taking other medicines

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

Some medicines reduce the contraceptive effectiveness of Cyprone 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 Cyprone 100 or may affect how well it works. You may need different amounts of your medicines, 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 this medicine.

HOW TO TAKE CYPRONE 100

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 box, ask your doctor or pharmacist for help.

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 Cyprone 100.

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.

How to take it

Swallow the tablets whole with a some liquid after meals.

When to take it

Take your medicine after meals 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. Missed Cyprone 100 tablets may diminish the effectiveness of treatment.

How long to take it

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

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 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 that you or anyone else may have taken too much Cyprone 100. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING CYPRONE 100

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Cyprone 100.

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

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 Cyprone 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 whilst taking Cyprone.

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 Cyprone 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 change 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 Cyprone 100 affects you.

Cyprone 100 may cause drowsiness and loss of concentration in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, tiredness and the ability to concentrate may be worse. The effectiveness of Cyprone to reduce abnormal sex drive can also be diminished under

the influence of alcohol. Alcohol may prevent Cyprone from working as well as it should in reducing abnormal sex drive.

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 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.

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:

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

These side effects are common.

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

Cyprone 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 immediately or go to Accident and Emergency at

your nearest hospital if you notice any of the following:

- 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

The above list includes serious side effects that may require medical attention or hospitalisation. Serious side effects are rare.

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.

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

You may not experience any of them.

AFTER TAKING CYPRONE 100

Storage

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

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

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

Do not store Cyprone 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 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

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

Available in packs of 50 tablets.

Ingredients

Cyprone 100 contains 100 mg of cyproterone acetate as the active ingredient.

It also contains the following inactive ingredients:

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

Cyprone 100 contains sucralose and sugars (as lactose). This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

Cyprone 100: AUST R 266553

This leaflet was prepared in September 2020.