

Cyprone

Cyproterone acetate

CONSUMER PRODUCT INFORMATION

What is in this leaflet

This leaflet answers some common questions about this medicine.

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 benefits and risks. Your doctor has weighed the risks of you taking Cyprone against the benefits they expect it will have 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 is used for

Cyprone is used for a number of conditions, as follows:-

- * in the treatment of women who have a problem with facial or chest hair, are balding, or have severe acne
- * in the treatment of men with cancer of the prostate gland
- * to reduce the sex drive of men with sexual deviations

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

Your doctor may have prescribed Cyprone for another purpose.

Cyprone is a hormone preparation that works by reducing the effects and the levels of male sex hormones in the body. [These male sex hormones are also produced by women in small amounts, and if the body produces too much or is overly sensitive, then masculine features can occur in women].

Cyprone is available only with a doctor's prescription.

There is no evidence that Cyprone is addictive.

Before you take Cyprone

Female patients should be aware that the long-term effects of Cyprone on fertility are not known.

Male patients should be aware that Cyprone causes a decrease in sperm count. It may take 3 to 20 months for the sperm count to return to normal once therapy has been stopped.

Patients should be aware that there have been reports of liver damage including liver failure, tumours and bleeding into the liver in patients receiving high doses of cyproterone acetate. Consult your doctor immediately if you experience upper abdominal pain, yellowing of the eyes or skin, itching, dark urine or generally feel unwell.

Before you start to take Cyprone, you must tell your doctor if

1. you have allergies to

- * Cyprone or cyproterone acetate
- * any other medicines, foods, dyes or preservatives
- * any of the ingredients listed at the end of this leaflet

2. you have, or have ever had, any other health problems or medical conditions, including:

- * a history of jaundice, persistent itching or herpes during pregnancy
- * liver disease or a tumour of the liver
- * a wasting disease
- * depression
- * a history of blood clots
- * diabetes
- * sickle-cell anaemia
- * Dubin-Johnson syndrome or Rotor syndrome

You may not be able to take Cyprone if you have any of these conditions.

3. you drink alcohol

If you are taking Cyprone to reduce your sex drive, alcohol may stop Cyprone working as well as it should.

4. you are or may be pregnant

CYPRONE MUST NOT BE TAKEN DURING PREGNANCY as it may lead to the development of female physical characteristics in male babies.

5. you are breastfeeding or wish to breastfeed

Cyprone passes into breast milk and must not be taken when breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Cyprone.

Do not take Cyprone if

- * the packaging shows any signs of tampering or does not look quite right
- * the use by date (Exp.) printed on the pack has passed

Do not give Cyprone to a child.

Taking other medicines

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

Some medicines may interfere with Cyprone. These include:

- * rifampicin
- * penicillins
- * medicines to control fits

These medicines may be affected by Cyprone or may affect how well Cyprone works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines you should not take with Cyprone.

Before treatment with Cyprone is started, you may need to have the following tests

Female patients should have a thorough medical and pelvic examination, including a Pap smear and breast examination.

Male patients may need to have a sperm count.

How to take Cyprone

Your doctor will decide the right dose for you.

Take Cyprone exactly as directed by your doctor.

The tablets should be taken with some liquid after a meal.

Women

1. Women taking combined therapy

In women of childbearing age, Cyprone is usually taken in courses together with another medicine which contains 50 micrograms of ethinyloestradiol. This combination of medicines also provides contraceptive protection.

Women taking the combined therapy should take their tablets at about the same time each day.

The tablets are taken in 28 day courses that follow the menstrual cycle.

Day 1 of the menstrual cycle is the first day of menstrual bleeding. Start tablet taking on day 1 of the menstrual cycle.

The following is an example of a course of therapy.

Days 1-10 (10 days)

One or two Cyprone 50 mg tablets plus one ethinyloestradiol 50 microgram tablet

Days 11-21 (11 days)

One ethinyloestradiol 50 microgram tablet

Days 22-28 and 1 (7 days)

Take no tablets (tablet-free week)

After 28 days, the next course is started on Day 5 of the next menstrual cycle.

Your course of medication may differ from this example. Take your medicine exactly as directed by your doctor.

During the tablet-free week, you should have a period. If you don't, you need to make sure you haven't fallen pregnant before resuming treatment.

You should start your next course exactly when it is due, even if you are still having a period.

If no bleeding occurs during the tablet-free week, or if frequent bleeding occurs at irregular intervals, see your doctor before starting the next course, as a pregnancy test may be needed.

As your condition improves, your doctor may reduce your dose of Cyprone. In this case, the contraceptive action of the combined therapy may not be as reliable. Another form of contraception (such as a condom or diaphragm) must be used. Your doctor will discuss this with you.

2. Women taking Cyprone alone

The usual dose is half to 1 Cyprone 50 mg tablet a day for 21 days, followed by a 7 day tablet-free break.

Men

For the treatment of cancer of the prostate, the usual daily dose is two Cyprone 50 mg tablets, taken either two or three times a day, after meals.

If you are taking Cyprone to reduce your sex drive, the usual starting dose is one Cyprone 50 mg tablet twice a day after meals. Some patients may need a larger dose.

If you forget to take it

It is important, especially in women taking the combined treatment of Cyprone and ethinyloestradiol, not to miss any doses. This is because Cyprone and ethinyloestradiol, when taken together, act as a contraceptive. Pregnancy must be avoided when taking Cyprone.

If women taking combined treatment miss a tablet by more than 12 hours, contraceptive protection in this cycle may be reduced.

An additional nonhormonal method of contraception (such as a condom or diaphragm) should be used for the rest of the course. Keep taking the Cyprone and ethinyloestradiol tablets for the rest of the current course, even if you have missed a tablet or tablets. Consult your doctor if no bleeding occurs in the tablet-free week.

For patients other than women taking combined treatment, 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 tablets as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

For men, it is also important not to miss any doses as prolonged absence may lead to conditions such as Osteoporosis.

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else may have taken too much Cyprone. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Cyprone

Female patients should be aware that acne usually responds sooner to treatment than excess hair or balding. Excess hair or balding may return when treatment is stopped.

Things you must do

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking Cyprone.

Make sure that all doctors, dentists and pharmacists who are treating you know that you are taking Cyprone.

Keep enough medicine to last weekends and holidays.

Tell your doctor if you are scheduled to have surgery.

Your doctor may ask you to have regular tests to check your liver, blood and other body functions.

Women taking the combined therapy who have a family history of breast cancer should have regular breast examinations.

Tell your doctor if you have diabetes.

Strict medical supervision may be needed.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Cyprone to treat any other complaints unless your doctor says so.

Things to be careful of

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

Cyprone may cause tiredness and reduced concentration in some people. Make sure you know how Cyprone affects you before you do anything that requires concentration, such as driving a car or operating machinery.

Be careful when drinking alcohol while you are taking Cyprone.

If you are taking Cyprone to reduce your sex drive, alcohol may stop Cyprone working as well as it should.

In women taking combined 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 the bleeding is heavy, consult your doctor immediately.

Female patients are encouraged not to smoke whilst taking combined Cyprone- ethinyloestradiol treatment. Use of any oral contraceptives may be associated with an increased risk of heart attack and stroke, and smoking can further increase this risk.

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

Side effects

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

Like all other medicines, Cyprone may 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.

Do not be alarmed by this list 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 if you experience any of the following side effects:

- * decreased or increased (more rare) sexual drive
- * tiredness, headache, depression
- * hot flushes
- * increase in weight

- * breast pain; breast enlargement and/or tenderness in males; oozing of milky fluid from the nipples
- * nausea, stomach upset
- * menstrual cycle changes in women, vaginal discharge; period pain
- * sleep disturbances
- * change in skin colour or appearance of rashes
- * fast heart rate
- * shortness of breath

Tell your doctor immediately or go to casualty at the nearest hospital if you notice any of the following. You may need urgent medical care.

- * severe pain and/or swelling in the stomach and gut
- * pain in the groin, chest or leg
- * swelling of one leg with tenderness or pain
- * coughing up blood or sudden shortness of breath
- * upper abdominal pain, yellowing of the eyes or skin (jaundice), itching, dark urine, feeling generally unwell and having a poor appetite. These may be due to problems with your liver.
- * allergic reactions such as skin rash or difficulty in breathing

Some additional side effects may occur in women taking the combined therapy. See your doctor immediately if you experience any of the following:

- * severe migraine headache for the first time, or a change in the pattern of your migraine
- * unusually bad headaches or if you have bad headaches more often than before
- * change or loss of eyesight
- * rise in blood pressure

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking Cyprone, even if it is not on this list.

After using Cyprone

Storage

Keep your tablets where children cannot reach them.

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

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

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

Do not store Cyprone or any other medicine in the bathroom or near a sink. Do not leave Cyprone in the car or on window sills.

Heat and dampness can destroy some medicines.

Do not take any tablets if they do not look quite right.

Disposal

If your doctor tells you to stop taking Cyprone, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Cyprone is a round white tablet marked CY/50 on one side and G on the other side.

Each pack contains either 20 or 50 tablets.

Ingredients

The active ingredient of Cyprone tablets is cyproterone acetate. Each Cyprone tablet contains 50 mg of cyproterone acetate.

The tablets also contain:

- * lactose
- * maize starch
- * povidone
- * colloidal anhydrous silica
- * magnesium stearate

The tablets are gluten free.

Supplier

Cyprone is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2
Wentworth Park Road
Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

The Australian registration number for Cyprone is Aust R 54562.

This leaflet was prepared on
15 September 2006