

Cyprone 50

contains cyproterone acetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Cyprone 50.

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 50 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 50 IS USED FOR

Cyprone 50 is an antiandrogenic hormone medication containing the active ingredient cyproterone acetate,

Androgens such as testosterone are natural male sex hormones which are also produced, to a slight extent, in females.

MEN:

In men, androgens may help cancer cells to grow in some types of prostate cancer. By blocking these hormones, Cyprone may slow or stop the growth of cancer. Cyprone may also 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.

Cyprone is also used to reduce abnormal sex drive in men.

WOMEN:

In women, androgens may increase hair growth, loss of scalp hair and secretion of oil from the sweat glands. By blocking these hormones, Cyprone may slow or stop excessive hairiness, loss of scalp hair, acne, oily skin and dandruff.

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

Cyprone 50 is only available on a doctor's prescription.

There is no evidence that Cyprone 50 is addictive.

BEFORE YOU TAKE CYPRONE

When you must not take it

Do not take Cyprone if you have an allergy to:

- Cyproterone acetate, the active ingredient in Cyprone
- 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

Cyprone should not be taken by children and adolescents below 18 years of age or girls who have not completed puberty.

Do not take this medicine if you are pregnant or suspect you may be pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Cyprone passes into breast milk and there is a possibility that your baby may be affected.

Do not take Cyprone if you have any of the following 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 or Rotor syndrome (your doctor would have told you if you have either of these conditions)
- History of jaundice (yellow skin or eyes), herpes or persistent itching during a previous pregnancy
- 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
- severe diabetes with blood vessel changes (your doctor would have told you if you have this)
- sickle-cell anaemia (your doctor would have told you if you have this)

Do not give this medicine to children.

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 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 you are pregnant or plan to become pregnant or are breastfeeding.

If taken during pregnancy, Cyprone may lead to signs of feminisation in the male foetus. Therefore, your doctor will check that you are not pregnant before you start taking Cyprone. Women should use a reliable form of contraception while taking Cyprone.

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

The long-term effects of Cyprone on female fertility are not known.

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

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 and Cyprone 50 may interfere with each other. These include:

- penicillins (antibiotic)
- rifampicin (antibiotic)
- anticonvulsants (medicines used to treat fits. Eg. phenytoin)
- antifungals (eg. ketoconazole, itraconazole, clotrimazole)
- ritonavir (a HIV treatment)
- St John's wort (a herbal remedy used to treat mood disorders)
- Statins (HMGCoA inhibitors), medicines used to lower cholesterol
- Medicines to treat diabetes

These medicines may be affected by Cyprone 50 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

HOW TO TAKE CYPRONE 50

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

The dosage of Cyprone 50 will be determined by your doctor.

Do not alter the dose yourself.

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

MEN:

Prostate cancer

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

Reduction of abnormal sex drive

Generally treatment is started with 50 mg of Cyprone twice daily and may be increased to 100 mg twice daily or three times daily before reducing gradually to the lowest effective dose. Your doctor may change your dose during treatment.

WOMEN:

If you are of childbearing age, you should commence your tablet taking on the 1st day of your cycle (= 1st day of bleeding). If you have no menstrual periods (amenorrhoea) your treatment can start immediately. In this case, the first day of treatment is to be regarded as the 1st day of the cycle.

Starting from day 1 take 50-100 mg (as advised by your doctor) of Cyprone daily from the 1st to the 10th day of the cycle (= for 10 days). Additionally, your doctor will advise the most appropriate contraceptive for you to take to provide the necessary contraceptive protection and to stabilise your cycle.

Your doctor will re-evaluate your treatment when you reach menopause. Long-term use (years) of Cyprone should be avoided.

If you are postmenopausal or have had a hysterectomy, Cyprone may be administered alone. The usual dose is 25-50 mg of Cyprone once daily for 21 days, followed by a 7-day tablet-free interval.

Shortness of breath may occur at high doses.

How to take it

Swallow the tablets whole with 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 tablets may diminish the effectiveness of treatment and may lead to breakthrough bleeding in women.

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 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.

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

If you are also taking an oral contraceptive and more than 12 hours has elapsed from the time Cyprone was due to be taken, note that contraceptive protection in this cycle may be reduced and thus there is an increased risk of becoming pregnant.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 many Cyprone 50 tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING CYPRONE 50

Things you must do

If you are about to start taking any new medicines, tell your doctor, dentists and pharmacist that you are taking Cyprone 50.

Keep all 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 and whenever any symptoms or signs suggesting liver problems are observed.

You may be required to have regular tests for liver, blood or other body functions.

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 Cyprone.

If you are a female taking an oral contraceptive during treatment, tell your doctor if your period does not occur during the tablet-free / placebo interval. Your doctor may need to check whether you are pregnant before you can continue treatment.

If you are a male taking Cyprone to reduce abnormal sex drive, you should consider undertaking additional measures such as therapy or counselling in order to take advantage of the period of reduced drive.

These measures may assist in achieving personal and social re-orientation.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Things you must not do

Do not take Cyprone 50 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

Cyprone 50 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 driving or operating machinery until you know how Cyprone 50 affects you.

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 Cyprone from working as well as it should in reducing abnormal sex drive.

Female patients should not smoke whilst taking combined Cyprone 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 Cyprone 50 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 Cyprone 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 Cyprone 50 to reduce your sex drive, alcohol may stop Cyprone 50 from working as well as it should.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cyprone 50.

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
- 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
- Menstrual cycle irregularity, spotting
- Hot flushes, sweating
- Shortness of breath
- Osteoporosis

If you were fertile before treatment, Cyprone will normally prevent sperm production in men and ovulation in women. In men, fertility is usually regained within a few months of discontinuing therapy. The long term effects on female fertility are not known.

In men Cyprone 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.

The above includes the more common side effects of your medicine

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

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 happen in some people.

- colloidal anhydrous silica
- pregelatinised maize starch

Sponsor

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AFTER TAKING CYPRONE 50

Storage

Keep your tablets in the 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 25 degrees Celsius.

Do not store Cyprone 50 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.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

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

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

Ingredients

Cyprone 50 contains 50 mg of cyproterone acetate as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- maize starch
- povidone
- magnesium stearate