

CYROTONE™

Cyproterone acetate 50 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about CYROTONE 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 CYROTONE 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 CYROTONE is used for

CYROTONE is an anti-androgenic hormone medication which has several different uses.

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, CYROTONE may slow or stop the growth of cancer.

CYROTONE can also be used in conjunction with other medications 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.

CYROTONE tablets are 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, CYROTONE 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.

CYROTONE is only available on a doctor's prescription.

There is no evidence that CYROTONE tablets are addictive.

Before you take CYROTONE

When you must not take it

Do not take CYROTONE if you have an allergy to:

- cyproterone acetate, the active ingredient in CYROTONE
- 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; or
- rash, itching or hives on the skin.

CYROTONE 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 CYROTONE passes into breast milk and there is a possibility that your baby may be affected.

Do not take CYROTONE 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 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).

CYROTONE tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CYROTONE.

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP". If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging 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 CYROTONE

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; or
- 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, planning to become pregnant or breastfeeding.

CYROTONE tablets should not be taken during pregnancy as it may lead to the development of female characteristics in male babies.

Therefore, your doctor will check that you are not pregnant before you start taking CYROTONE. Women should use a reliable form of contraception while taking CYROTONE.

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

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

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

Taking other medicines

If you are taking other medicines you must tell your doctor or pharmacist. This includes medicines that you can buy without a prescription from a pharmacy, supermarket or a health food shop.

Your doctor or pharmacist will be able to tell you what you should do when you have to take other medicines while you are on CYROTONE.

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

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

How to take CYROTONE tablets

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 pack, ask your doctor or pharmacist for help.

How much to take

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

Reduction of abnormal sex drive

Generally treatment is started with 50 mg of CYROTONE 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 CYROTONE 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.

If you are postmenopausal or have had a hysterectomy, CYROTONE may be administered alone. The usual dose is 25-50 mg of CYROTONE 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 a meal.

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 CYROTONE 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 effects.

If you are also taking an oral contraceptive and more than 12 hours has elapsed from the time CYROTONE 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 Poisons Information Centre (telephone 13 11 26 - Australia) for advice, or go to the casualty department at your nearest hospital, if you think that you or anyone else may have taken too many CYROTONE tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

While you are taking CYROTONE tablets

Things you must do

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking CYROTONE tablets.

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.

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 CYROTONE 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.

Things you must not do

Do not give CYROTONE tablets to anyone else, even if they have the same condition as you.

Do not use CYROTONE tablets to treat any other medical complaints unless your doctor tells you to.

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 CYROTONE tablets affect you.

This medicine 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.

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 CYROTONE to reduce abnormal sex drive can also be diminished under the influence of alcohol.

Side effects

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

All medicines can have side effects. 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 the following lists of side effects.

You may not experience any of them.

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;
- weight change;
- headache;
- depressive mood;
- nausea and other gastrointestinal complaints;
- decreased sexual drive;
- breast pain, change in breast size, breast swelling and/or tenderness;
- menstrual cycle irregularity, spotting;
- hot flushes, sweating;
- shortness of breath; or

- osteoporosis.

If you were fertile before treatment, CYROTONE 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 CYROTONE 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 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; or
- 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.

After using CYROTONE tablets

Storage

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

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

Keep CYROTONE tablets in a cool dry place where the temperature stays below 30°C.

Do not store CYROTONE tablets or any other medicine in the bathroom or near a sink.

Do not leave CYROTONE tablets in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep CYROTONE tablets 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

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date. Ask your pharmacist what to do with any tablets left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

CYROTONE are white to off-white round, flat tablets engraved "50", with a break line on one side and plain on the other side.

CYROTONE* is presented in bottles and blisters containing either 20 or 50 tablets.

*Some pack sizes and presentations may not be marketed.

Ingredients

Active ingredient:

cyproterone acetate

Inactive ingredients:

- lactose;
- microcrystalline cellulose;
- croscarmellose sodium;
- povidone; and
- magnesium stearate.

Distributor

Eris Pharmaceuticals (Australia) Pty Ltd

6 Eastern Road

South Melbourne VIC 3205

www.eris-pharma.com.au



Cyrotone 50 mg tablet blister pack AUST R

184194

Cyrotone 50 mg tablet bottle AUST R 184196

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