

CYPROCUR 50 TABLETS

cyproterone acetate 50 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about CYPROCUR 50 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 CYPROCUR 50 tablets 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 the medicine.

You may need to read it again.

What CYPROCUR 50 tablets are used for

CYPROCUR 50 tablets are an anti-androgenic hormone medication containing the active ingredient cyproterone acetate, which is used to treat cancer of the prostate gland.

It can also be used in conjunction with other medications or 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.

Androgenic hormones are generally required for cancer of the prostate gland to grow.

CYPROCUR 50 tablets work in two ways. Firstly, they stop the androgenic hormones (testosterone) present in your body from being able to attach to the cancer cells. Secondly, they decrease the amount of androgen hormone present in your blood stream by an effect on the hormonal mechanisms that control androgen production by the body.

CYPROCUR 50 tablets can also be used to reduce the sex drive of men with sexual deviations.

It is also used in the treatment of women who have a problem with facial or chest hair, are balding or have severe acne.

CYPROCUR 50 tablets are only available on a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take it

When you must not take it

Do not take CYPROCUR 50 if you are allergic to:

- cyproterone acetate
- any other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take this medicine if you are pregnant.

CYPROCUR 50 tablets should not be taken during pregnancy as it may lead to the development of female characteristics in male babies.

Your doctor should carry out a thorough gynaecological and medical examination before starting treatment to exclude pregnancy.

Female patients should be aware that the long term effects of CYPROCUR 50 tablets on fertility are not known.

Do not take this medicine if you are breast feeding.

Do not give CYPROCUR 50 tablets to children.

Do not take CYPROCUR 50 tablets after the expiry date printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take it if the packaging shows signs of tampering or the tablets do not look quite right.

Talk to your doctor if you are not sure whether you should start taking this medicine.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you:

- are pregnant or breastfeeding
- have a history of herpes of pregnancy
- have liver disease. Your doctor should perform a blood test to check your liver before starting you on CYPROCUR 50 tablets and again if liver disease is suspected
- suffer from or have a history of jaundice or persistent itching during a previous pregnancy
- have ever suffered from blood clots in the leg, stroke or heart attack
- have severe diabetes that has damaged your blood vessels
- have sickle-cell anaemia
- have hypertension
- have suffered from severe chronic depression
- have Dubin-Johnson syndrome or Rotor syndrome.

For males, tell your doctor if fertility after treatment is important.

In this case, it is advisable to have a sperm count before taking CYPROCUR 50 to establish your fertility before commencing therapy, as this medicine can cause a decrease in sperm count. It may take between 3 to 20 months for the sperm count to return to normal once therapy has been stopped.

If you have not told your doctor about any of the above, tell them before you start taking CYPROCUR 50 tablets.

Taking other medicines

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

Some medicines interfere with CYPROCUR 50 tablets. These include:

- penicillins (antibiotic).
- rifampicin (antibiotic).
- anticonvulsants, medicines used to treat fits.

These medicines may be affected by CYPROCUR 50 tablets or may affect how well it works.

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

How to take it

Follow all directions given to you by your doctor.

How much to take

Your initial dose will depend on the condition being treated and your response to the medicine. Your doctor may gradually reduce the dose for maintenance therapy.

How to take it

Swallow the tablet, with some liquid, after meals.

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 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 your nearest hospital, if you think that you or anyone else may have taken too many CYPROCUR 50 tablets.

Do this even if there are no signs of discomfort or poisoning.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CYPROCUR 50, especially if you are starting any new medicines.

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

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

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

Things you must not do

Do not take CYPROCUR 50 tablets to treat any other medical complaints unless your doctor tells you to.

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

Things to be careful of

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

CYPROCUR 50 tablets may cause drowsiness and loss of concentration in some people.

If you are taking CYPROCUR 50 tablets to reduce your sex drive, alcohol may stop CYPROCUR 50 tablets from working as well as it should.

Female patients should not smoke whilst taking combined CYPROCUR 50 tablets/ ethinyloestradiol treatment.

Female patients should be aware that the contraceptive action of the combined treatment of CYPROCUR 50 tablets 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 CYPROCUR 50 tablets/ 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.

Side effects

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

All medicines can have side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

The most common side effect is tiredness and loss of concentration which may affect your ability to drive or operate machinery.

CYPROCUR 50 tablets may occasionally result in gynaecomastia (swelling of the breast area which is sometimes also associated with tenderness or sensitivity of the breast area to touch), diminished libido, changes in body weight, nausea, allergy, depressive moods, headache, shortness of breath and blood clotting (which may lead to a clot on the lungs, stroke or heart attack) and increase in blood pressure in women.

In males, if you were fertile before treatment, CYPROCUR 50 may also result in your inability to produce sperm (infertility). Fertility is usually regained within a few months of discontinuing therapy. This medicine 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.

Yellowing of the skin/eyes, darkening of the urine and abdominal pain or swelling should be all reported immediately to your doctor.

In very rare cases, liver tumours may lead to life-threatening bleeding into the stomach. You must inform your doctor of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time.

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

Other side effects not listed above may happen in some people.

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

You may not experience any of them.

After taking it

Storage

Keep CYPROCUR 50 tablets in a cool dry place 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.

Do not store CYPROCUR 50 tablets or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

CYPROCUR 50 are white, round tablets with a break line on one side.

Available in packs of 20 or 50 tablets.

Ingredients

Active ingredient:

Each CYPROCUR 50 tablet contains 50 mg of cyproterone acetate.

Inactive ingredients:

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

CYPROCUR 50 tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd

34-36 Chandos St
St Leonards, NSW 2065

Australian registration number: AUST R 178007.

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