

GenRx Cyproterone Acetate 50 mg Tablets

contains the active ingredient, cyproterone (SYE-proe-te-rone) acetate 50 mg

For a copy of a large print leaflet ph: 1800 195 055

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about cyproterone acetate.

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 this medicine against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What cyproterone acetate is used for

The name of your medicine is GenRx Cyproterone Acetate 50 mg. It contains the active ingredient cyproterone acetate which is an anti-androgenic hormone medication. It inhibits the influence of male sex hormones (androgens) which are also produced, to a slight extent, in females. It also has a progestational and anti-gonadotrophic effect.

It is used for a treat a number of conditions like:

- * 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. It 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.
- * To reduce the sex drive of men with sexual deviations.

How it works

This medicine is a hormone preparation that works by reducing the effects and the level of male sex hormones in the body. These works in two ways. Firstly it stops the androgen hormones (testosterone) present in your body from being able to attach to the cancer cells. Secondly by an effect on the hormonal mechanisms that control androgen production by the body, it decreases the amount of androgen hormone present in your blood stream.

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

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

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take cyproterone acetate

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

A thorough medical and pelvic examination, including a Pap smear and breast examination must be done before treatment.

Other causes of androgenisation e.g. Cushing's syndrome; ovarian tumours, adrenal carcinoma and androgenital syndrome should have been ruled out. Pregnancy must be excluded before starting treatment in women of childbearing potential. The long-term effects on female fertility are not known with certainty.

Male patients should be aware that cyproterone acetate 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. Male patients may need to have a sperm count.

Direct hepatic toxicity, including jaundice (yellow skin and eyes), hepatitis and hepatic failure, which has been fatal in some cases, has been reported in patients treated with 200 -

300 mg cyproterone acetate. Most reported cases are in men with prostate cancer. Toxicity is dose-related and develops, usually, several months after treatment has begun. Your doctor will order liver function tests before you start taking cyproterone acetate and whenever any symptoms or signs suggestive of hepatotoxicity occur. If you develop any of these signs you're your doctor immediately.

If you suffer from diabetes, tell your doctor as you will need to be kept under close observation, and your requirements for oral antidiabetics or insulin can change.

If your occupation demands great concentration (e.g. road users, machine operators) you should note that cyproterone acetate can lead to tiredness and diminished vitality and can impair the ability to concentrate.

When you must not take it

Do not take this medicine if

- * **you have had an allergic reaction to cyproterone acetate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

- * **you suspect you may be pregnant.**

Appropriate contraception should be commenced before starting this medicine to prevent pregnancy and control the menstrual cycle. You should discuss this with your doctor before taking this medicine.

This medicine **MUST NOT BE TAKEN DURING PREGNANCY**. If taken during pregnancy, the properties of the preparation may lead to signs of feminisation in the male foetus.

Therefore, your doctor will check that you are not pregnant before you start taking cyproterone acetate. Your doctor will also prescribe ethinyloestradiol, probably in the form of the "pill" (e.g. Diane-35 ED) to be taken as well to ensure contraception.

- * **you are breast-feeding.**

This medicine 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 this medicine.

- * you have a disease of the liver
- * you have a history of or currently have a liver tumour (in carcinoma of the prostate only if these are not due to metastases i.e. to the spread of your cancer)
- * you have a history of jaundice (yellow skin or eyes) or persistent itching during a previous pregnancy
- * you have a history of herpes of pregnancy
- * you have Dubin-Johnson or Rotor syndrome. (Your doctor would have told you this).
- * you have a wasting disease (with the exception of carcinoma of the prostate)
- * you have severe chronic depression
- * you have previous or existing thromboembolic processes (blockage of the blood vessels by blood clots)
- * you have severe diabetes with vascular changes
- * you have sickle-cell anaemia. (Your doctor would have told you this)

However, if you have inoperable prostatic carcinoma as well as a history of thromboembolic processes or are suffering from sickle-cell anaemia or from severe diabetes with vascular changes, your doctor would have discussed with you the benefits and risks of using cyproterone acetate in the situation.

This medicine should not be used before the conclusion of puberty since an unfavourable influence on stature and hormonal function cannot be ruled out.

If you are taking cyproterone acetate for your sex drive, alcohol may stop it working as well as it should.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may have not worked as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or it does not look quite right.

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 or pharmacist.

Taking other medicines

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

Some medicines and cyproterone acetate may interfere with each other. These include:

- * rifampicin
- * penicillins
- * medicine to control fits
- * medicine to treat diabetes
- * cholesterol-lowering medicine

These medicines may be affected by cyproterone acetate or may affect how well it works. You may need different amounts of your medicines.

Your doctor or pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or to avoid while taking cyproterone acetate.

Other interactions not listed above may also occur.

You may not be able to take this medicine if you drink alcohol. If you are taking this medicine to reduce your sex drive, alcohol may stop this medicine working as well as it should.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends on your condition.

The dose of GenRx Cyproterone Acetate 50 mg will be determined by your doctor.

How to take it

Tablets should be taken with some liquid after meals.

When to take it

Take your medicine 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 to remember when to take it.

If you forget to take it

If it is almost time for you to take 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 continue taking your tablets as usual.

Do not take a double dose to make up for the dose you missed. Thus

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 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 your nearest hospital, if you think that you or anyone else may have taken too much cyproterone acetate.

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

You may need urgent medical attention.

Keep telephone numbers of these services handy.

While you are using cyproterone acetate

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking cyproterone acetate.

Tell your doctor immediately if you become pregnant,

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

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

If you develop any signs of hepatotoxicity - yellow skin or eyes - tell your doctor immediately. If hepatotoxicity is confirmed, cyproterone acetate will normally be

withdrawn, unless hepatotoxicity can be explained by another cause, e.g. metastatic disease (spread of your cancer); in which case cyproterone acetate should be continued only if the perceived benefit outweighs the risk.

As with other sex steroids benign and malignant liver tumours have been reported in isolated cases. In very rare cases liver tumours may lead to life-threatening intra-abdominal haemorrhage. If you develop severe upper abdominal complaints or tenderness tell your doctor immediately.

A sensation of shortness of breath may occur in individual cases under high-dosed treatment with cyproterone acetate. If this occurs, tell your doctor.

In extremely rare cases, the occurrence of thromboembolic events has been reported in temporal association with the use of cyproterone acetate. However, a causal relationship has not been established.

Women

If, during the combined treatment, slight "unscheduled" bleeding occurs during the 3 weeks per cycle in which the tablets are being taken, do not stop taking your tablets. However, if the bleeding is heavy, you should consult your doctor.

Men

The sexual drive-reducing effect of cyproterone acetate can be diminished under the influence of alcohol.

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

Female patients who are taking the combined GenRx Cyproterone Acetate 50 mg / ethinyloestradiol treatment who have a family history of breast cancer should have regular breast examinations.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used in the surgery.

Things you must not do

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

Do not use this medicine to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affect you. This medicine may cause drowsiness and loss of concentration in some people.

Female patients should not smoke whilst taking combined GenRx Cyproterone Acetate 50 mg / ethinyloestradiol treatment. Use of any oral contraceptives may be associated with an increased risk of heart attack and stroke.

Female patients should be aware that the contraceptive action of the combined treatment of GenRx Cyproterone Acetate 50 mg 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 condom or diaphragm should be used for the remainder of the cycle. In women taking combined GenRx Cyproterone Acetate 50 mg / 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 unusual bleeding continues or if bleeding is heavy, consult your doctor immediately.

Be careful when drinking alcohol while you are taking this medicine to reduce your sex drive. Alcohol may stop GenRx Cyproterone Acetate 50 mg from working as well as it should.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

Infertility and impotence are expected effects of cyproterone acetate and cannot generally be avoided.

The most common side effects that may occur are:

- * tiredness
- * weight increase
- * decreased sexual drive.

Less common are:

- * headache
- * depressive moods
- * blood clotting (which may lead to a clot on the lungs, stroke or heart attack)
- * nausea, stomach upset
- * menstrual cycle changes in women, vaginal discharge; period pain
- * gynaecomastia (swelling of the breast area which is sometimes also associated with tenderness or sensitivity of the breast area to touch)

Over the course of several weeks, cyproterone acetate gradually restricts the man's ability to procreate. This ability is usually regained within a few months of discontinuing therapy.

In male patients, cyproterone acetate occasionally leads to breast enlargement (sometimes combined

with tenderness to touch of the breast) which usually regresses after withdrawal of the preparation or reduction of the dose.

As with other antiandrogenic treatments, in male patients long-term androgen deprivation with cyproterone acetate may lead to osteoporosis in very rare cases.

In women, ovulation is inhibited under the combined treatment so that a state of infertility exists. A feeling of tension in the breasts may occur.

In individual cases, disturbances of liver function, some of them severe, have been reported with high-dosed cyproterone acetate treatment. Tell your doctor immediately if you notice signs such as jaundice (yellow skin and eyes).

Cyproterone acetate may occasionally result in:

- * unusual secretion of breast milk
- * sleep disturbances
- * hot flushes
- * fast heart rate
- * menstrual cycle changes in women, vaginal discharge; period pain
- * diminished libido or increased (rare) sexual drive
- * change in skin colour or appearance of rashes
- * allergic reactions

Tell your doctor immediately or go to the 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 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 had headaches or if you have had 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 any other effects what is making you feel unwell while you are taking, or soon after you have finished taking GenRx Cyproterone Acetate 50 mg tablets, even if it is not on this list.

After taking this medicine

Storage

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

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

Keep your medicine in a cool dry place where the temperature stays below 30 degrees C. Protect from light

Do not store your medicine 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 can not 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.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product Description

What GenRx Cyproterone Acetate 50 mg Tablets look like

GenRx Cyproterone Acetate 50 mg are white round tablets engraved 50 with a breakline on one side, plain on the other side.

GenRx Cyproterone Acetate 50 mg tablets are presented in bottles, either 20 tablets or 50 tablets.

Ingredients

GenRx Cyproterone Acetate 50 mg contains 50 mg of cyproterone acetate as the active ingredient.

As well as its active ingredient, GenRx Cyproterone Acetate 50 mg contains:

- * lactose
- * cellulose microcrystalline
- * croscarmellose sodium
- * povidone
- * magnesium stearate.

This medicine is gluten-free, and does not contain sucrose, tartrazine or any other azo dyes.

Australian Registration Number

GenRx Cyproterone Acetate 50 mg Tablets: AUST R 101534.

Sponsor

Apotex Pty Ltd
 ABN 52 096 916 148
 66 Waterloo Road
 North Ryde NSW 2113
 Australia

GenRx is a registered trademark of Apotex Pty Ltd.

This leaflet was prepared in June 2008 and updated in January 2009.