

GenRx Cyproterone Acetate

100 mg Tablets

contains the active ingredient, cyproterone (SYE-proe-te-rone) acetate 100 mg

Consumer Medicine Information

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

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.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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 100 mg. It contains the active ingredient cyproterone acetate which is 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 "hot flushes" or "sweats" and to prevent any initial worsening of the disease.

How it works

Some types of cancer of the prostate gland requires androgenic hormones to grow. This medicine 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.

This medicine should only be taken by men. It should not be taken by women or children.

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.

Before you take cyproterone acetate

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 contact 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.

Do not take this medicine if:

- 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 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.

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 work 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:

- phenytoin, a medicine used to treat epilepsy
- medicines used to treat fungal infections, including ketoconazole, itraconazole, clotrimazole
- ritonavir, a medicine used in the treatment of HIV
- rifampicin, a bactericidal antibiotic used to treat infections such as tuberculosis and leprosy
- St John's wort, a herbal remedy used to treat mood disorders

- penicillins
- medicines used to treat diabetes
- statins (HMGCoA inhibitors), medicines for cholesterol-lowering medicine for people with or at risk of cardiovascular disease.

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 pack, 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 100 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. This 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.

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.

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

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 affects you. This medicine may cause drowsiness and loss of concentration in some people.

Be careful when drinking alcohol while you are taking this medicine to reduce your sex drive. Alcohol may stop this medicine 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 GenRx Cyproterone Acetate 100 mg and cannot generally be avoided.

The most common side effects that may occur are:

- tiredness
- loss of concentration which may affect your ability to drive or operate machinery.

Cyproterone acetate may occasionally result in:

- breast pain, breast enlargement and or tenderness in males; oozing of milky fluid from the nipples
- increases in body weight
- diminished libido
- nausea, stomach upset
- sleep disturbances
- change in skin colour or appearance of rashes,
- fast heart rate
- allergy
- headache
- depressive moods

This medicine will also normally result in the inability to get or maintain an erection (impotence). This ability is usually regained within a few months of discontinuing therapy.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the skin and/or eyes
- severe upper abdominal pain
- shortness of breath

The above list includes serious side effects that may require medical attention. Serious side-effects are rare.

If the following happens, tell your doctor immediately or go to your nearest hospital:

- sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling.

The above is a serious side effect. You may need urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

Tell your doctor if you notice any other effects while taking this medicine.

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°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 100 mg Tablets look like

GenRx Cyproterone Acetate 100 mg are white round tablets engraved 100 with a breakline on one side, plain on the other side.

GenRx Cyproterone Acetate 100 mg tablets are presented in blister packs containing 50 tablets.

Ingredients

GenRx Cyproterone Acetate 100 mg contains 100 mg of cyproterone acetate as the active ingredient.

As well as its active ingredient, GenRx Cyproterone Acetate 100 mg contains:

- lactose
- microcrystalline cellulose
- 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
100 mg Tablets: AUST R 101535.

Sponsor

Apotex Pty Ltd
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Australia

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