

PATIENT INFORMATION LEAFLET

CYPROTERONE ACETATE 50 mg & 100 mg TABLETS

(cyproterone acetate)

The name of this medicine is Cyproterone Acetate 50 mg and 100 mg Tablets, which will be referred to as Cyproterone Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet please tell your doctor or pharmacist. See section 4

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1. WHAT CYPROTERONE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in your tablets is cyproterone acetate, which belongs to a group of medicines called anti-androgens. These work by blocking the actions of male sex hormones (androgens) which are released naturally in your body. They also reduce the production of androgens.

It has been shown that the growth of tumours of the prostate gland may be dependent on male hormones. Since cyproterone acetate blocks the action of androgens and reduces the amount of androgens produced by the body, it can be used to help relieve the symptoms of a tumour of the prostate gland.

It can also be taken by males to control an over active sex drive.

2. BEFORE YOU TAKE CYPROTERONE TABLETS

Do not take Cyproterone Tablets if you:

- **are allergic (hypersensitive)** to cyproterone acetate, or any of the **other ingredients** in Cyproterone Tablets (these are listed in section 6, Further Information)
- **are under 18 years of age**
- **have ever been diagnosed with a meningioma** (a generally benign tumor of the tissue layer between the brain and the skull). You should ask your physician if you are in doubt.
- have kidney failure
- have liver disease (including Dubin-Johnson syndrome and Rotor syndrome) Malignant tumours (except for carcinoma of the prostate) Previous or existing liver tumours (only if these are not due to metastases from carcinoma of the prostate)

If you are being treated for an overactive sex drive you should not take this medicine if you:

- suffer from liver disease
- have or have previously had **tumours**, other than in your prostate gland
- suffer from any **illness making you thin, weak or tired**
- have a history of **blood clots** (heart attack, stroke, thrombosis or embolism)
- suffer from **diabetes**
- suffer from a condition called **sickle cell anaemia** (abnormalities of the red blood cells)
- have or have ever suffered from **depression**

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Take special care with Cyproterone Tablets

Before you take Cyproterone Tablets you should tell your doctor if you:

- have liver disease
- have a history of blood clots (heart attack, stroke, thrombosis or embolism)
- suffer from diabetes
- suffer from a condition called sickle cell anaemia (abnormalities of the red blood cells)
- have or have ever suffered from depression
- drink alcohol even if it is not regularly
- are planning a family

If you are a diabetic and your doctor decides that it is still alright for you to take Cyproterone Tablets, the dose of your medicine used to treat your diabetes (oral diabetic treatments or insulin), may be altered. It is likely that your doctor will arrange regular blood tests whilst you are taking Cyproterone Tablets. If you are being treated for an overactive sex drive, your doctor may check your sperm count before and during treatment. Whilst Cyproterone Tablets may reduce the production of sperm, the medicine must **not** be used instead of contraception.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Certain medicines can interfere with the effectiveness of each other. It is particularly important to tell your doctor or pharmacist before taking this medicine if you are also on:

- thiazolidinediones, pioglitazone and rosiglitazone used in the treatment of diabetes
- ketoconazole, itraconazole, clotrimazole used to treat fungal infections
- rifampicine used to treat tuberculosis
- phenytoin used to treat epilepsy
- ritonavir used to treat HIV infection and AIDS
- St Johns Wort (Hypericum perforatum), a herbal remedy
- cholesterol-lowering drugs such as statins.

Taking your medicine with food and drink

Cyproterone Tablets should be taken after meals. You should avoid drinking alcohol whilst taking these tablets.

Pregnancy and breast-feeding

This medicine is not for use in women.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate tools or machines because this medicine may make you feel tired or weak particularly within the first few weeks of taking it.

Important information about some of the ingredients of Cyproterone Tablets

This product contains **lactose**. If you have been told by your doctor that you have **an intolerance to some sugars** contact your doctor before taking this medicine.

3. HOW TO TAKE CYPROTERONE TABLETS

Always take Cyproterone Tablets exactly as your doctor has told you to do so. You should check with your doctor or pharmacist if you are not sure.

Dosage

For adults and the elderly, the dose for Cyproterone Tablets is dependent on the condition for which your doctor has prescribed them.

For the control of an overactive sex drive the usual dose is 50 mg twice a day.

Your doctor can only prescribe this medicine once he has explained what the tablets will do and you have agreed to take them.

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Cyproterone Acetate 50mg & 100mg Tablets
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To help relieve the symptoms of a prostate cancer the usual doses are as follows:

- to reduce the possible worsening of a prostate cancer, which can happen during the first few weeks of starting other treatments for prostate cancer, the usual daily dose is two 50 mg tablets twice daily (200 mg) alone for 5-7 days, followed by two 50 mg tablets twice daily (200 mg) for 3-4 weeks together with another medicine.
- in long term treatment where other treatments or surgery are unsuitable, the usual daily dose is 200 mg to 300 mg (one 100 mg tablet or two 50 mg tablets twice or three times a day).
- to treat hot flushes caused by other treatments for prostate cancer or following surgical removal of the testicles, the usual daily dose is 50 mg to 150 mg (one 50 mg tablet once or three times a day).
Cyproterone Tablets are not recommended for use in male children and adolescents below 18 years of age.

Method of administration

Cyproterone Tablets should be taken by mouth after meals.

If you take more Cyproterone Tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

If you forget to take Cyproterone Tablets

If you miss a dose do not worry. Take another as soon as you remember and then go on as before. Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cyproterone Tablets can cause side effects, although not everybody gets them. If you get any of the following symptoms after taking these tablets you **should contact your doctor or pharmacist immediately**:

- **any sudden wheeziness, difficulty in breathing or dizziness, skin rashes**
- **yellowing of the whites of the eyes or skin**
- **severe pain in the stomach or chest area**

The following side effects have been reported

Very common (probably affecting more than 1 in 10 people)

- reduced sexual drive and potency
- reduction of sperm count and volume of ejaculation

Common (probably affecting more than 1 in 100 people)

- depressive moods and restlessness
- increase or decrease in body weight which can be associated with fluid retention
- shortness of breath
- liver problems, some of them severe or even fatal have been reported with high-dosed cyproterone acetate treatment (200-300 mg daily)
- discomfort or enlargement of the breasts
- hot flushes, sweating, tiredness

Uncommon (probably affecting fewer than 1 in 10 people)

- rash

Rare side effects (probably affecting fewer than 1 in 1000 people):

- allergic reactions
- tender lumps in the breasts and in rare cases secretion of milk from the nipples may occur. These symptoms usually disappear when treatment is stopped

Very rare (probably affecting fewer than 1 in 10,000 people)

- some forms of liver cancer (malignant liver tumours) which may lead to bleeding in the abdomen

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The following side effects with unknown frequency have also been reported:

- the occurrence of meningiomas has been reported in association with longer term use (years) of cyproterone acetate at doses of 25 mg/day and above
- thromboembolic events (formation of blood clots), benign and malignant liver tumors
- symptoms of osteoporosis (fragile, weak bones, which are easily broken)
- changes in blood caused by a type of anaemia (feeling of weakness, tiredness). These side effects will usually go away after you have been taking your tablets for a few weeks
- dryness of the skin, scalp and hair
- increased growth of hair on the head but reduced hair growth on the body
- lightening of hair colour
- female type of pubic hair growth

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **United Kingdom** Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CYPROTERONE TABLETS

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date (Exp.) stated. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C. Store your tablets in the original package. Keep blisters in the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cyproterone Tablets contain:

Cyproterone Tablets contains 50 mg or 100 mg of the active ingredient cyproterone acetate.

The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch, povidone, magnesium stearate and colloidal anhydrous silica.

What Cyproterone Tablets looks like and the contents of the pack:

Cyproterone Acetate 50 mg Tablets are white, circular tablets with a central break line on one side and plain on the other. Cyproterone Acetate 50 mg Tablets are available in a pack size of 56 tablets. Cyproterone Acetate 100 mg Tablets are white capsule shaped tablets with a breakline on one side and CPA 100 marked on the other. Cyproterone Acetate 100 mg Tablets are available in a pack size of 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Kent Pharma UK Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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