

PACKAGE LEAFLET: INFORMATION FOR THE USER

CYPROTERONE ACETATE 100 mg tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cyproterone Acetate 100mg tablets is and what it is used for
2. What you need to know before you take Cyproterone Acetate 100mg tablets
3. How to take Cyproterone Acetate 100mg tablets
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1. WHAT CYPROTERONE ACETATE TABLETS IS AND WHAT IT IS USED FOR

What is Cyproterone Acetate tablets?

Cyproterone Acetate tablets is a medicine containing cyproterone acetate. It is an anti-androgen therapy. It blocks the actions of male sex hormones (androgens) and reduces the amount of male sex hormones produced by the body.

What is Cyproterone Acetate tablets used for?

Cyproterone Acetate tablets is used in men to treat prostate cancer.

This medicine is used:

1. to reduce the possible worsening of the disease which may occur when you start other treatments used for prostate cancer
2. for long term treatment of prostate cancer when surgery or other medicines are not suitable
3. to treat hot flushes which may occur during treatments with other medicines used for prostate cancer or following surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CYPROTERONE ACETATE TABLETS

Do not take Cyproterone Acetate tablets:

- If you have liver diseases (including previous or existing liver tumours (unless these are due to secondary cancers caused by prostate cancer), Dubin-Johnson Syndrome or Rotor Syndrome)
- If you have any type of cancer (other than cancer of the prostate gland)
- If you have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull). You should ask your doctor if you are in doubt
- If you have wasting diseases (diseases involving an unintended loss of weight or muscle) except for prostate cancer that cannot be operated on
- If you have blood clots (thrombosis or embolism)

or:

- If you are **allergic** to cyproterone acetate or any of the other ingredients of this medicine (listed in section 6)
- if you are under 18 years old or if your testes or bones are not yet fully formed.

Warnings and precautions

Talk to your doctor before taking Cyproterone Acetate tablets.

Several **blood tests or checks** may be required while you are taking this medicine:

- **liver problems**, some of them severe or even fatal, have been reported with cyproterone acetate treatment. Your doctor may arrange for you to have regular liver tests before and during treatment to monitor this and may stop your treatment if necessary. See also section 4.
- using medicines such as Cyproterone Acetate tablets has very rarely been linked to the development of **benign (nonmalignant) liver tumours** and with some forms of liver cancer (malignant liver tumours). Liver tumours may lead to bleeding in the abdomen, which can be life-threatening. **If you have any new stomach discomfort or pain that does not go away quickly, you must tell your doctor straightaway.**
- **blood clots** have been reported in patients taking this medicine which may also be linked to the reason you are taking Cyproterone Acetate tablets. **Tell your doctor** if any of the following apply to you, as you may be at an increased risk of getting a blood clot.
If you have: – a history of blood clots, strokes or heart attacks
– abnormal red blood cells (sickle –cell anaemia)
– severe diabetes that affects your blood circulation

- **if you suffer from severe depression**, this may get worse whilst you are taking Cyproterone Acetate tablets. **(See your doctor if you are affected by this)**

- **effects on the blood (anaemia)** have been reported rarely during long term treatment with this medicine. See also section 4.

- **shortness of breath** has been reported in patients taking this medicine at high doses (300 mg daily)
- Cyproterone Acetate tablets can alter the sugar levels in your blood. **If you are diabetic, check your blood sugar levels regularly.** Your doctor may alter the dose of medicine used to treat your diabetes.
- Your doctor will check the function of your adrenal glands, as they may become suppressed during treatment with Cyproterone Acetate tablets. Symptoms may include tiredness, fatigue, loss of appetite, weight loss, low blood sugar, low blood pressure, dehydration, headache, irritability and depression, aching muscles, abdominal pain, a craving for salty foods, feeling or being sick and diarrhoea.

Other medicines and Cyproterone Acetate tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may stop Cyproterone Acetate tablets from working properly. Also Cyproterone Acetate tablets, may change the way other medicines you are taking are broken down in your body.

Tell your doctor if you take any other medicines regularly, especially:

- medicines such as rifampicin for the treatment of tuberculosis
- medicines such as phenytoin used to treat epilepsy or other illnesses
- products containing the herbal remedy commonly known as St-John's wort (*Hypericum perforatum*)
- medicines such as ketoconazole, itraconazole, clotrimazole for the treatment of fungal conditions
- medicines such as ritonavir used to treat HIV infections
- cholesterol-lowering drugs such as statins. Cyproterone Acetate tablets may make the side effects of statins worse, for example the breakdown of muscle
- medicines such as glitazones used to treat diabetes.

If you are diabetic your doctor may need to alter the dose of medicine required to treat your diabetes. See also section 2 "Warnings and precautions".

Driving and using machines

You may feel tired and weak during treatment. If affected, do not drive, operate machinery or do anything where these symptoms may put either yourself or others at risk.

Important information about some of the ingredients in Cyproterone Acetate tablets

Cyproterone Acetate tablets contains Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CYPROTERONE ACETATE TABLETS

Your doctor will decide what dose you will take. **Always take this medicine exactly as your doctor has told you.** Check with your doctor if you are not sure. Take the tablets after meals and swallow them whole with a drink of water.

The usual dose range is from 1 tablet once a day (100 mg) up to 1 tablet three times a day (300 mg).

If you take more Cyproterone Acetate tablets than you should

As soon as you can, talk to your doctor who will tell you what you need to do. There have been no reports of serious illness from taking too much Cyproterone Acetate tablets in a single dose.

If you forget to take Cyproterone Acetate tablets

If you forget to take a dose, take it as soon as you remember and take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cyproterone Acetate tablets

Do not reduce the dose or stop taking your tablets unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have trouble breathing or swallowing, this may be a sign of a rare allergic reaction - **contact your doctor or go to a hospital straight away**.

These are the possible side effects of Cyproterone Acetate tablets, starting with the more common ones:

Very common - may affect more than 1 in 10 people

- decreased sex drive
- impotence
- reduced sperm count
- reduced volume of ejaculate

Common - may affect up to 1 in 10 people

- weight decrease or increase, which can be associated with fluid retention
- depressed mood
- restlessness
- breast swelling sometimes with tenderness
- hot flushes, sweating
- tiredness
- shortness of breath
- liver problems, some of them severe or even fatal, have been reported with dosages of 100 mg and above of cyproterone acetate treatment. Your doctor may arrange for you to have regular liver tests during treatment to monitor this and may stop your treatment if necessary

Uncommon - may affect up to 1 in 100 people

- rash

Rare - may affect up to 1 in 1,000 people

- allergic reaction (possibly causing a rash, itching or more rarely shortness of breath. If you have trouble breathing or swallowing, contact your doctor or go to a hospital straight away)
- tender lumps in the breasts and oozing of milky fluid from the nipples. These effects usually disappear if treatment is stopped or if the dose of Cyproterone Acetate tablets is reduced

Very rare - may affect up to 1 in 10,000 people

- benign (non-malignant) liver tumours, see also section 2 "Warnings and precautions"
- some forms of liver cancer (malignant liver tumours). Liver tumours may lead to bleeding in the abdomen, which can be life-threatening. If you have any new stomach discomfort or pain that does not go away quickly, you must tell your doctor straightaway

Effects of Cyproterone Acetate tablets on sperm

After you have been taking this medicine for some months, you may not have any sperm in your ejaculate.

You will probably become unable to make anyone pregnant, but note that this does **not** happen at once.

Do not rely on this medicine for contraception at any time. While the overall number of sperm that you produce will be reduced, more of your sperm than usual will be abnormal in shape. Some people think these abnormal sperm might possibly produce abnormal babies. Your doctor will be able to advise you further if you are thinking of having children.

Other changes that have been reported include:

- blood clots have been reported in patients taking this medicine but they have not definitely been linked to Cyproterone Acetate tablets. See also section 2 "Warnings and precautions"
- the occurrence of meningiomas (a generally benign tumour of the tissue layer between the brain and the skull) has been reported in association with longer term use (years) of Cyproterone Acetate tablets at doses of 25 mg per day and above
- dry skin and improvement in acne
- temporary patchy loss of body hair, a reduction in hair growth on the body, an increased growth of hair on the head, lightening of hair colour, a female type of pubic hair growth
- effects on the blood (anaemia) have been reported rarely during long term treatment with this medicine. Your doctor may arrange for you to have regular blood tests during treatment to monitor this
- thinning of the bones (osteoporosis)
- tiredness, fatigue, loss of appetite, weight loss, low blood sugar, low blood pressure, dehydration, headache, irritability and depression, aching muscles (often muscle weakness), abdominal pain, a craving for salty foods, feeling or being sick and diarrhoea (suppressed adrenal glands).

After stopping treatment

After stopping treatment, the decrease in sex drive, reduction in sperm count and breast swelling will generally go back to normal.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CYPROTERONE ACETATE TABLETS

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on both the outer carton and on each blister strip of tablets after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cyproterone Acetate tablets contains

- the active ingredient is cyproterone acetate. Each tablet contains 100 mg of cyproterone acetate.
- the other ingredients are: lactose, maize starch, povidone, colloidal anhydrous silica and magnesium stearate (E572).

What Cyproterone Acetate tablets looks like and contents of the pack

Your medicine is a white, oblong tablet marked "C 1" on one side and with a score-line on both sides.

Cyproterone Acetate 100mg tablets is available in packs containing 84 tablets.

Marketing Authorisation Holder:

STRAGEN UK Limited, Castle Court, 41 London Road, Reigate, Surrey, RH2 9RJ, United Kingdom

Manufacturer:

Haupt Pharma GmbH, Schleebrüggenkamp 15, Munster, D-48159 Germany

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