Tell your doctor
Acetate tablets, may change the way other medicines you are taking are broken down in your body.
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.
Read all of this leaflet carefully before you start taking this medicine because it contains important
information for you.
1. WHAT CYPROTERONE ACETATE TABLETS IS AND WHAT IT IS USED FOR
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.
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CYPROTERONE ACETATE TABLETS
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
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brain and the skull). You should ask your doctor if you are in doubt
If you have been taking for long period of time or have had treatment with the use of other medicines
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.
Possible 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. See section 4.
Cyproterone Acetate tablets can alter the sugar levels in your blood.
• If you have diabetes (including previous or existing liver tumours (unless these are due to secondary cancers
casted 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 any of the following conditions: mild or moderate liver disease, mild or moderate kidney disease,
• You should report any of the following conditions:
• If you have diabetes, check your blood
• 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 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 may be required while you are taking this medicine:
• several times, 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
(labour) as a gender assignment and with some forms of liver cancer (complications of cancer in the liver).
Others that affect your blood circulation
• if you have high blood pressure, you should be treated with Cyproterone Acetate tablets.
• severe diabetes that affects your blood circulation
• you may have tiredness, fatigue, loss of appetite, weight loss, low blood
can be life-threatening. If you have any new stomach
• 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)
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can be life-threatening. If you have any new stomach
• 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)
Other changes that have been reported include:
• thinking of having children.

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 protect you from getting pregnant.

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 growth of hair, especially on the face, can be reduced.
- the growth of breast tissue sometimes with tenderness, can be reduced.

Do not report to 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:
- 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 100 mg tablets is available in packs containing 84 tablets.

Marketing Authorisation Holder:
STRAGEN UK Limited, Castle Court, 41 London Road, Reigate, Surrey, RH2 9JR, United Kingdom
Manufacturter:
Haupt Pharma GmbH, Schleibrüggenkamp 15, Munster, D-48159 Germany

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