

# CYPRON TABLET

Cyproterone Acetate (50mg)

## What is in this leaflet

1. What Cypron Tablet is used for
2. How Cypron Tablet works
3. Before you use Cypron Tablet
4. How to take it
5. While you are using it
6. Side Effects
7. Storage and Disposal of Cypron Tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Cypron Tablet is used for

Cypron Tablet is used to control sexual desire in men who have sexual deviation and anti-androgen treatment in prostate cancer.

In women, it is used to control abnormal growth of hair on the face and body and severe hair loss, usually accompanied by severe acne and/or accumulation of scales of greasy skin.

## How Cypron Tablet works

Cypron Tablet 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.

## Before you use it

Do not take Cypron Tablet

If you have:

- liver diseases (including previous or existing liver tumours, Dubin-Johnson Syndrome or Rotor syndrome)
- wasting diseases (diseases involving an unintended loss of body weight or muscle)
- blood clots (thrombosis or embolism) or have ever had these
- severe diabetes that affects your blood circulation
- abnormal red blood cells (sickle-cell anaemia)
- severe depression for many months
- a history of jaundice or persistent itching during a previous pregnancy, a history of herpes virus infection of pregnancy

## -When you must not take it

- if you are allergic (hypersensitive) to cyproterone acetate or any of the other ingredients of Cypron Tablet
- If you are under 18 years old or if your testes or bones are not yet fully formed.

## -Before you start to take it

Your doctor may ask you to sign a witnessed agreement to treatment before prescribing Cypron Tablet. You may also have a test to check the number and function of your sperm before you start treatment as Cypron Tablet can cause the overall number of sperm you produce to reduce.

## Take special care with Cypron:

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.
- using medicines such as Cypron Tablet has very rarely been linked to the development of liver tumours (including non-malignant and malignant forms). 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 people taking this medicine. 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
  - cancer
  - abnormal red blood cells (sickle-cell anaemia)
  - severe diabetes that affects your blood circulation
- shortness of breath has been reported in people taking this medicine at high doses.

- Cypron Tablet 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 Cypron Tablet.

## Pregnancy and Breastfeeding

Cypron Tablet should not be used during pregnancy or breastfeeding.

## -Taking other medicines

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

Some medicines may stop Cypron Tablet from working properly. Also Cypron Tablet 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:

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

## **How to take it**

### -How much to take

Your doctor will decide what dose you will take depending on your situation.

# CYPRON TABLET

Cyproterone Acetate (50mg)

To control sexual desire in men, the usual dose range is from 1 tablet twice a day (100mg) up to 2 tablets three times a day (300mg).

In women of child-bearing potential, two 50 mg tablets are to be taken daily from the 1st-10<sup>th</sup> day of the cycle (1st day of your cycle = 1st day of bleeding).

Once the desired effect is achieved, your dose may be gradually lowered. Additionally, your doctor will advise the most appropriate contraceptive for you to take to provide the necessary contraceptive protection and to stabilise your cycle.

If you are postmenopausal or have had a hysterectomy, Cypron may be taken alone. The usual dose is 25-50 mg once daily for 21 days, followed by a 7-day tablet-free interval

Always take Cypron Tablet exactly as your doctor has told you. Check with your doctor if you are not sure.

### -When to take it

Take the tablet after your meals and swallow it whole with a drink of water.

### -How long to take it

Always take Cypron exactly as your doctor has told you. You should check with your doctor if you are not sure.

### -If you forget to take it

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 missed one table for more than 12 hours, contraceptive protection may be reduced.

### -If you take too much (overdose)

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 Cypron in a single dose.

### **While you are taking it**

#### -Things you must do

If you have any questions on the use of this product, ask your

doctor or health care provider or pharmacist.

#### -Things you must not do

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

#### -Things to be careful of

##### Taking with food and drink

Cypron does not work well in men who regularly drink a lot of alcohol.

##### 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.

### **Side Effects**

Like all medicines, Cypron 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 Cypron Tablet:

Very common

- reduced sperm count
- reduced sexual desire in men

Common

- weight decrease or increase
- depressed mood
- restlessness
- breast swelling sometimes with tenderness
- hot flushes, sweating
- tiredness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### **Storage and Disposal of Cypron Tablet**

#### -Storage

Store below 25°C. Protect from light and moisture.

#### -Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

### **Product Description**

#### -What it looks like

Cypron Tablet 50 mg are white, round, flat tablet marked 50 with a score line on one face, plain on the other.

#### -Ingredients

Active ingredient

The active ingredient is cyproterone acetate. Each tablet contains 50mg of cyproterone acetate.

Inactive ingredients

Other ingredients include lactose, cellulose microcrystalline, croscarmellose sodium, povidone, magnesium stearate, purified water

#### -MAL Number

MAL10120022AC

### **Manufacturer**

Douglas Pharmaceuticals Limited  
Central Park Drive and Corner Te  
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### **Product Registration Holder**

Actavis Sdn Bhd  
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