

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDROCUR

50 mg tablet

CYPROTERONE ACETATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Androcur is and what it is used for
2. What you need to know before you take Androcur
3. How to take Androcur
4. Possible side effects
5. How to store Androcur
6. Contents of the pack and other information

1. WHAT ANDROCUR IS AND WHAT IT IS USED FOR

What is Androcur?

Androcur 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 Androcur used for?

Androcur is used to control sexual desire in men who have an increased sex drive (hypersexuality) and/or sexual deviation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANDROCUR

Your doctor may ask you to sign a witnessed agreement to treatment before prescribing Androcur. You may also have a test to check the number and function of your sperm before you start treatment as Androcur can affect this. The overall number of sperm you produce will be reduced and more sperm than usual will be abnormal in shape.

Do not take Androcur

If you have:

- liver diseases (including previous or existing liver tumours, Dubin-Johnson syndrome or Rotor syndrome)
- any type of cancer (other than cancer of the prostate gland)
- 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

- wasting diseases (diseases involving an unintended loss of 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 which you have had for many months

or if:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Androcur

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 Androcur 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 receiving Androcur. 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
- 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)
- Androcur 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 Androcur. 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 Androcur

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

Some medicines may stop Androcur from working properly. Also Androcur 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.

Androcur 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 section 2 'Warnings and precautions'.

Androcur with food, drink and alcohol

Androcur 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.

Important information about some of the ingredients in Androcur

Androcur contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking this medicinal product.

3. HOW TO TAKE ANDROCUR

Your doctor will decide what dose you will take depending on your treatment. Always take this medicine exactly as your doctor has told you.

Check with your doctor if you are not sure.

R The usual dose is 1 tablet twice a day. Once the desired effect is achieved, your dose may be gradually lowered.

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

Androcur is not for use in youths under 18 years old.

If you take more Androcur 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 Androcur in a single dose.

If you forget to take Androcur

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 Androcur

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.

For information on drinking alcohol while taking this medicine, see under Androcur with food, drink and alcohol in section 2.

These are the possible side effects of Androcur, starting with the more common ones:

Very common - may affect more than 1 in 10 people

- 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. 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 Androcur 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 Androcur on sperm

After you have been taking this medicine for some months, you may not have any sperm in your ejaculate. You will probably be 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 Androcur. 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 Androcur 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 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE ANDROCUR

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton 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 Androcur contains:

- the active ingredient is cyproterone acetate. Each tablet contains 50 mg of cyproterone acetate
- the other ingredients are: maize starch, povidone 25000, magnesium stearate (E572), lactose, silicon dioxide (aerosil) (E551).

What Androcur looks like and contents of the pack

Each pack of Androcur contains 56 round, white tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bayer plc, Bayer House
Strawberry Hill
Newbury
Berkshire RG14 1JA
United Kingdom

Manufacturer:

Bayer Pharma AG Berlin, Germany
or
Delpharm Lille SAS Lys Lez Lannoy, France
or
Bayer Weimar GmbH und Co KG Weimar, Germany

This leaflet was last revised in May 2015.

Other formats:

To listen or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Androcur 50 mg	00010/0519

This is a service provided by the Royal National Institute of the Blind.