

Package leaflet: Information for the user

Androcur® 100 mg Tablets

cyproterone acetate

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 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

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.

Androcur is used in men to treat prostate cancer where surgery is not an option.

Androcur is also used to control sexual desire in men who have a sexual deviation. You should only take Androcur, if your doctor considers that other interventions are inappropriate.

2. What you need to know before you take Androcur

Do not take Androcur

For control of sexual drive

If you have:

- liver diseases (including previous or existing liver tumours), Dubin-Johnson or Rotor syndromes
- 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)
- severe depression which you have had for many months
- blood clots (thrombosis or embolism) or have ever had these
- severe diabetes that affects your blood circulation
- abnormal red blood cells (sickle-cell anaemia)

or if:

- you are allergic to cyproterone acetate or any of the other ingredients of this medicine (listed in section 6).

For prostate cancer:

If you have:

- liver diseases (including previous or existing liver tumours), Dubin-Johnson or Rotor syndromes
- 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)
- severe depression which you have had for many months
- blood clots (thrombosis or embolism) or have ever had these

or if:

- you are allergic to cyproterone acetate or any of the other ingredients of this medicine (listed in section 6).

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:

- meningioma (a generally benign tumour of the tissue layer between the brain and the skull). Use of Androcur has been linked to the development of meningioma. The risk increases especially when you use it for longer duration (several years) or for a shorter duration with high doses (25 mg per day and above). If you are diagnosed with meningioma, your doctor will stop your treatment with cyproterone acetate (see section 'Do not take Androcur'). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.
- **liver problems**, some of them severe or even fatal, have been seen with Androcur treatment (at doses of 100mg daily or above). 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 Androcur has very rarely been linked to the development of **benign (non-malignant) liver tumours and liver cancer (malignant 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 but they have not definitely been

linked to 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

- **effect on the blood (anaemia)** Your doctor may arrange for you to have regular blood tests during treatment to monitor this.
- 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
- **shortness of breath** has been reported in patients taking this medicine, but this does not normally need treatment
- your **adrenocortical function** should be checked regularly.

Children and adolescents

Androcur is not for use in youths under 18 years old

Other medicines and Androcur

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

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.

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 alcohol

When used to control sexual drive, Androcur does not work as well in men who drink alcohol, as the alcohol can affect behaviour.

Pregnancy, breast-feeding and fertility

Androcur is not for use in women.

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.

Androcur 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 Androcur

A specialist will decide if treatment with Androcur is necessary, for how long and what dose you should 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.

- When used in prostate cancer, the usual dose is half or 1 tablet once or twice a day (total daily dose of 50mg to 200mg), but your doctor may increase the dose. The maximum dose is 1 tablet three times a day (300mg).
- To control sexual drive, the usual starting dose is half a tablet (50mg) twice a day (total daily dose of 100mg). Your doctor may increase or decrease the dose depending on the response to treatment. The maximum dose is 1 tablet (100mg) three times a day.
- Take the tablet after your meals and swallow it whole with a drink of water.

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.

Some serious side effects, and related symptoms, are described under section 2 'Warnings and precautions'.

Please also read this section carefully and see your doctor if appropriate.

If you have any new stomach discomfort or pain that does not go away quickly, you must tell your doctor straight away (See Section 2: 'What you need to know before you take Androcur').

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 alcohol** in section 2 'What you need to know before you take Androcur'.

These are the possible side effects of Androcur, 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
- shortness of breath
- liver problems including a yellowish discoloration of the skin (*jaundice*), hepatitis or liver failure
- breast swelling sometimes with tenderness
- tiredness
- hot flushes
- sweating

**Uncommon -
(may affect up to 1 in 100 people)**

- rash

**Rare -
(may affect up to 1 in 1,000 people)**

- meningiomas (a generally benign tumour of the tissue layer between the brain and the skull)
- allergic reaction

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

- benign (non-malignant) liver tumours and some forms of liver cancer (malignant liver tumours).

**Not known –
(frequency cannot be estimated from the available data):**

- 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
- 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'
- 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.**

- thinning of the bones (*osteoporosis*).

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.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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 both the outer carton and on each blister strip of tablets after the letters 'EXP'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 100mg cyproterone acetate
- The other ingredients are: lactose monohydrate (see section 2 'Androcur contains lactose'), magnesium stearate (E572), maize starch, povidone 25,000.

What Androcur looks like and contents of the pack

The white to faintly yellow oblong tablets are marked with 'LA' on both sides of the break-line and a six-sided figure on the back. The tablets can be broken into equal halves.

Each pack of Androcur contains 60 tablets

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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