

PACKAGE LEAFLET: INFORMATION FOR THE USER

Androcur 10, tablets 10 mg
cyproterone acetate

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

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1. WHAT IS ANDROCUR 10 AND WHAT IS IT USED FOR?

Each tablet of Androcur 10 contains the hormone cyproterone acetate. A hormone is a substance that exerts a very specific effect on one or more organs in the body. The hormone cyproterone acetate has an anti-androgenic effect: it inhibits the action of male hormones (androgens). Androgens are produced by both men and women, although much less in women.

In women, an excess of androgens manifests itself, among other things, in the form of excessive hair growth (hirsutism; excessive hair growth in a male pattern: on the legs, arms, chest, and face). Androgens also stimulate the activity of the sebaceous glands (glands that secrete sebum, an oily substance), making the skin oily and potentially causing acne (pimples).

The cyproterone acetate in Androcur 10 reduces excessive hair growth and inhibits the stimulating effect of androgens on the sebaceous glands. As a result, the skin becomes less oily and fewer pimples (these are clogged and/or inflamed sebaceous glands) will develop.

During treatment with Androcur 10, the function of the ovaries is suppressed, and it is possible that no ovulation occurs. When you stop using Androcur 10, the function of the ovaries is no longer inhibited.

- Androcur 10 is used for the treatment of excessive hair growth (hirsutism). Additionally, it is used for severe forms of acne (pimples). You should only use this medication when no satisfactory results have been achieved with drugs containing a lower dose of cyproterone acetate or with other treatments.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

- if you are pregnant or breastfeeding
- if you have a liver disorder:
 - you have a liver disease such as the Dubin-Johnson syndrome or Rotor syndrome
 - you have a benign or malignant liver tumor, or have had one in the past
 - you have had jaundice (idiopathic pregnancy jaundice) or persistent itching (pruritus gestationis) during a previous pregnancy
- if you have a meningioma (a generally benign tumor in the membrane between the brain and skull) or have had one in the past.
- if you have had a blistering rash (herpes gestationis)
- if you are physically very weakened and have lost a lot of weight and muscle strength (cachexia); this may be the case if you have a malignant tumor
- if you have a long-lasting (chronic) and severe depression (you are (severely) despondent and pessimistic)
- if you have or have had a blood clotting disorder (thromboembolic disorder)
- if you have a severe form of diabetes (diabetes mellitus) where your blood vessels are affected
- if you have sickle cell anemia (a hereditary disorder of the red blood cells)
- if you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If in doubt, contact your doctor before using this medicine.

Note: If you need to use a contraceptive pill in addition to Androcur 10, you must also consider the side effects, warnings, interactions with other (medicinal) products of that pill, and the situations in which you should not use that pill. Therefore, also follow the relevant instructions from the contraceptive pill's leaflet.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine.

Be extra careful with this medicine:

- if you are still young and your menstrual cycle (the occurrence of your periods) is not yet regular
- if you have diabetes: during the use of Androcur 10, you will need to visit your doctor more frequently for check-ups because the need for the medications you use for this (tablets or insulin) may change. Consult your doctor to see if it is necessary to adjust the amount of medication.

The use of cyproterone acetate has been associated with the development of a usually benign brain tumor (meningioma). The risk increases especially when you use the medicine for a long time (several years) or for a shorter time in high doses (25 mg per day or more). If a meningioma is diagnosed, your doctor will stop your treatment with cyproterone acetate (see section 'When

should you not use this medicine?'). If you notice symptoms such as changes in vision (e.g., double vision or blurred vision), hearing loss or ringing in the ears, loss of smell, headaches that worsen over time, memory loss, seizures, weakness in your arms or legs, you should immediately inform your doctor.

Before you start taking Androcur 10, your doctor will perform various tests. A breast examination will be done, and a smear test (examination of the cervical mucus) will be made. Before you can start with Androcur 10, it must be established that you are not pregnant. Even if your menstruation stops during treatment with Androcur 10, a pregnancy test will be done before you can continue with the treatment.

Before and during the treatment, your blood pressure and weight will be monitored, and the doctor will (have) your urine and blood and the functioning of your liver and adrenal cortex examined.

For long-term use of Androcur 10, it is recommended to repeat these tests every 6 months.

In patients treated with Androcur 10, liver function disturbances have occurred. Therefore, your doctor will check your liver function before starting the treatment and during the treatment. Symptoms including jaundice, liver inflammation (hepatitis), and abnormal liver function may indicate liver damage. If liver damage is detected, your doctor will discontinue your treatment with Androcur 10.

There is no evidence that fertility is negatively affected after stopping treatment with Androcur 10.

Because the cyproterone acetate in Androcur 10 reduces the secretion of sebum, it is possible that your skin becomes dry.

The use of Androcur 10 in combination with a contraceptive pill

During treatment with Androcur 10, you must not become pregnant. In women of childbearing age, the use of Androcur 10 should be combined with a contraceptive pill. If you need to use a contraceptive pill in addition to Androcur 10, you should also consider the side effects, warnings, interactions with other (medicines) of that pill, and the situations in which you should not use that pill. Therefore, also follow the relevant instructions from the contraceptive pill's leaflet.

If you use Androcur 10 (with or without a contraceptive pill) and have a condition that can worsen during pregnancy, you need extra monitoring. This includes the following conditions: epilepsy, otosclerosis (a hereditary form of deafness), multiple sclerosis (a disease of the central nervous system, resulting in reduction/loss of various body functions), porphyria (a disorder in the production of the red pigment of the blood, causing, among other things, the skin to become sensitive to light), tetany (a condition with muscle cramp attacks), diabetes, and high blood pressure.

If you need to vomit or have diarrhea within a few hours after taking Androcur 10 and the contraceptive pill, you should follow the special instructions in the contraceptive pill's leaflet.

If you experience light bleeding (spotting: blood drops or spots) outside the pill-free week (of the contraceptive pill), you should not stop taking the tablets. If the bleeding outside the pill-free week is heavier or if it recurs, the cause should be investigated.

If you need to undergo surgery, have to rest in bed for some time, or are not allowed to walk (for example, if one of your legs is cast or bandaged due to the treatment of varicose veins), it is recommended to stop using Androcur 10 and the contraceptive pill 6 weeks before the surgery or (bed) rest period. This is due to a potentially increased risk of thrombosis (the formation of a blood clot that can block a blood vessel).

Are you using any other medicines?

Are you using any other medicines besides Androcur 10, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

If you need to use a contraceptive pill in addition to Androcur 10, you should also consider the (medicines) that may interact with it. See the contraceptive pill's leaflet for this.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, you should not use Androcur 10.

Do you think you are pregnant or do you want to become pregnant? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

During the first weeks of treatment with Androcur 10, you may sometimes feel tired and your concentration may be reduced. Keep this in mind when driving and using machines.

Androcur 10 contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Take the Androcur 10 tablets at about the same time each day, if necessary with some liquid (water). The tablets should be swallowed whole.

A strip of Androcur 10 contains 15 tablets.

When should you take Androcur 10?

Women of childbearing age (approximately between 12 and 50 years) with a regular menstrual cycle

If you are not yet taking a contraceptive pill, your doctor will give you a prescription for one. During treatment with Androcur 10, you must not become pregnant. A contraceptive pill provides protection against pregnancy and also (again) a regular menstrual cycle (the regularity with which you have your periods).

Before starting Androcur 10, it must be certain that you are not pregnant. It may therefore be necessary to take a pregnancy test. Your doctor can tell you more about this.

- If you are not yet using a contraceptive pill, you should start with the first tablet of the contraceptive pill on the first day of your period. You are then protected against pregnancy from the 1st day.
- In addition, during the 1st to the 15th day that you use your contraceptive pill, take 1 tablet of Androcur 10 each day.
- After these fifteen days, take only the contraceptive pill from the 16th to the 21st day. These are the last six tablets of the strip.
- Then do not take a tablet for 7 days. During these 7 tablet-free days (also called the stop or pause week), a bleeding should start. This so-called 'withdrawal bleeding' (a menstruation-like bleeding) usually begins on the 2nd or 3rd day of the pause week.
- Start on the 8th day after the last tablet of your contraceptive pill with the next strip and with taking Androcur 10, even if the bleeding has not yet ended.
This means that you start a new strip on the same day of the week each time, and also that the withdrawal bleeding occurs approximately on the same days each month.

Absence of bleeding

o If you do not get a bleeding during the break week, you should not continue with a new strip of your contraceptive pill or with Androcur 10 before you or your doctor have done a pregnancy test and it is certain that you are not pregnant.

Women of childbearing age (approximately between 12 and 50 years) with an irregular menstrual cycle

If you have an irregular menstrual cycle (the times when you get your periods are unpredictable), or if you have not had a period for a few months, it must first be established that you are not pregnant.

If you are not pregnant, you can start with Androcur 10 and a contraceptive pill immediately, but you are not protected against pregnancy from the first day of use. Therefore, during the first 7 days that you use Androcur 10 and a contraceptive pill, you must use an additional contraceptive (for example, a condom).

Take 1 tablet of Androcur 10 every day from the 1st to the 15th day that you use your contraceptive pill.

For further treatment, follow the instructions under 'Women of childbearing age (...) with a regular menstrual cycle'.

Women in menopause

If you are in menopause, you do not need to use Androcur 10 in combination with a contraceptive pill. Your doctor will tell you how many tablets you should use.

Women who no longer have a uterus

If your uterus has been surgically removed, you do not need to use Androcur 10 in combination with a contraceptive pill. Your doctor will tell you how many tablets you should use.

Your doctor will tell you how long you should use Androcur 10. The duration of treatment with Androcur 10 depends on the severity of the symptoms (of excessive hair growth, acne, or oily skin). In general, improvement will be visible after 6-9 months in cases of excessive hair growth. For acne and oily skin, this is often earlier.

If you notice that Androcur 10 is too strong or not strong enough, consult your doctor or pharmacist.

Have you used too much of this medicine?

There have been no reports of serious harmful effects from taking many Androcur 10 tablets at the same time.

If you have used or taken too much Androcur 10, contact your doctor or pharmacist immediately.

Have you forgotten to use this medicine?

If you forget to take a tablet of Androcur 10, this may reduce the effectiveness of the treatment. Forgetting a tablet can also lead to irregular bleeding (spotting or light bleeding). Skip the missed Androcur 10 tablets (do not take a double dose to make up for the missed tablet) and take the next Androcur 10 tablets at the usual time, with your contraceptive pill.

What to do if you forget your contraceptive pill

- If you are less than 12 hours late in taking a tablet, the effectiveness of the contraceptive pill is not reduced. Take that tablet as soon as you remember and take the next tablets at the usual time.
- If you are more than 12 hours late in taking a tablet, the effectiveness of your contraceptive pill may be reduced. In this case, follow the instructions regarding missed pills as stated in the package leaflet of your contraceptive pill.

What to do in case of unexpected bleeding

If unexpected bleeding occurs (spotting or breakthrough bleeding) during the three weeks you are taking your contraceptive pill and/or Androcur 10, do not stop taking the tablets.

The irregular bleeding usually stops once your body has become accustomed to the pill (after about 3 strips). If it lasts longer, worsens, or starts again, you should contact your doctor.

What to do if the expected bleeding does not occur

If you do not have a withdrawal bleed during the pill-free week after forgetting Androcur 10 and your contraceptive pill, you may be pregnant. Contact your doctor immediately. Do not continue with Androcur 10 and your contraceptive pill until your doctor has confirmed that you are not pregnant.

If you stop using this medicine

If you stop using Androcur 10, the symptoms for which you started this medication may return.

Other information for special patient groups

Children and adolescents up to 18 years

Androcur 10 may only be used in female patients after puberty.

Older patients

Androcur 10 is intended only for women of childbearing age.

Patients with impaired liver function

Androcur 10 should not be used if you have a liver disorder (as long as your liver is not functioning adequately). See also section 'When should you not use this medicine?'

Patients with impaired kidney function

There is no data indicating that the dose needs to be adjusted if you have impaired kidney function.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately if you experience any of the following symptoms:

- sudden severe pain in your upper abdomen that does not quickly and spontaneously disappear.
- feeling unwell, fever, nausea, vomiting, loss of appetite, itching all over the body, yellowing of your skin and eyes, light-colored stools, dark-colored urine. These may be signs of liver toxicity, including inflammation of the liver (hepatitis).

The side effects reported by users of Androcur 10 are listed below:

Rare (occur in less than 1 in 1000 users):

- meningioma (a usually benign tumor of the tissue layer between the brain and skull)

Unknown (based on available data, the frequency cannot be determined):

- benign and malignant liver tumors
- hypersensitivity reaction
- weight gain or weight loss
- abnormal liver function, jaundice, liver inflammation (hepatitis)
- depressive mood, restlessness (temporary), decrease in libido (sexual desire), increase in libido (sexual desire)
- bleeding in the abdominal cavity
- skin rash
- tender breasts, inhibition of ovulation, light bleeding (for further information on light bleeding see section 2 under 'The use of Androcur 10 in combination with a contraceptive pill' in the subsection 'When should you be extra careful with this medicine?')

In combined treatment with a contraceptive pill, ovulation is inhibited, making you infertile during treatment. Additionally, fatigue may occur.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands

Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date. It can be found on the label on the packaging after

'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is cyproterone acetate. Each tablet contains 10 milligrams of cyproterone acetate.
- The other substances in this medicine are: lactose monohydrate, maize starch, povidone 25 (E1201), colloidal anhydrous silica (E551), and magnesium stearate (E470b).

What does Androcur 10 look like and what is in a package?

- Androcur 10 tablets are white to light yellow tablets with a score line on one side and the letters 'BW' in a hexagon on the other side. The tablets are round and have a diameter of 7 millimeters.
- Androcur 10 is available in packages of 15 tablets in a blister.

Marketing authorization holder and manufacturer

Registration holder:

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging): Brocacef B.V., Maroastraat 43, 1060 LG Amsterdam
or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:

Bayer Weimar GmbH und Co. KG

Döbereiner Strasse, 20

99427 Weimar

Germany

Registered under

RVG 120911//09078

Androcur 10, tablets 10 mg (Portugal)

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