

PRODUCT NAME: ANDROCUR 50 mg and ANDROCUR 100 mg
APPLICANT: BAYER (PTY) LTD
DOSAGE FORM: TABLETS
STRENGTH: 50 mg and 100 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ANDROCUR 50 mg and ANDROCUR 100 mg Tablets

Cyproterone acetate

Contains sugar: Androcur 50 mg – 105,5 mg lactose per tablet

Androcur 100 mg – 184,3 mg lactose per tablet

Read all of this leaflet carefully before you start taking ANDROCUR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ANDROCUR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours

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 use 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 hormone preparation that blocks the effects of androgen, which are sex hormones produced in males but also – to a lesser extent – in females. The active substance is cyproterone acetate.

In addition to ANDROCUR, your doctor may prescribe a progestogen-oestrogen contraceptive to provide contraceptive protection and cycle stabilization. During combined treatment ovarian function is blocked. These changes are reversible after stopping treatment.

In women, **ANDROCUR 50 mg** tablets are used for severe signs of androgenisation such as

- very severe hirsutism (increased facial and body hair),
- androgen-dependent severe loss of scalp hair eventually resulting in baldness (severe androgenetic alopecia),
- severe forms of acne and/or seborrhoea.

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In males, **ANDROCUR 50 mg and 100 mg** tablets are used for

- Reduction of drive in sexual deviations
- Antiandrogen treatment in inoperable prostate cancer.

2. What you need to know before you take ANDROCUR

Do not use ANDROCUR

Do not take ANDROCUR if you have any of the conditions listed below. If any of these apply to you, tell your doctor before you start taking ANDROCUR.

In females

- if you are pregnant or breastfeeding
- if you have a liver disease
- if you had a history of jaundice or persistent itching during a previous pregnancy
- if you had a history of herpes of pregnancy
- if you suffer from hereditary disturbances of liver function with impaired excretion of the red blood cell pigment called bilirubin (“Dubin-Johnson Syndrome” or “Rotor-Syndrome”)
- if you have or ever had a benign or malignant liver tumour
- if you have a wasting disease (a disease-causing decay or loss of strength)
- if you suffer from severe chronic depression
- if you have or ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels (thromboembolic process)
- if you have severe diabetes mellitus with blood vessel changes
- if you have sickle-cell anaemia
- if you are hypersensitive (allergic) to cyproterone acetate or any of the other ingredients of ANDROCUR
- If your doctor prescribes a progestogen-estrogen contraceptive in combination with ANDROCUR, attention is also drawn to the information contained in the package insert of the progestogen-estrogen contraceptive.

In males

- if you have a liver disease
- if you suffer from hereditary disturbances of liver function with impaired excretion of the red blood cell pigment called bilirubin (“Dubin-Johnson Syndrome” or “Rotor-Syndrome”)
- if you have or ever had a benign or malignant liver tumour (only if these are not due to metastases from carcinoma of the prostate).
- if you have or ever had a benign brain tumour (meningioma)
- if you have a wasting disease (a disease-causing decay or loss of strength, with the exception of inoperable carcinoma of the prostate)
- if you suffer from severe chronic depression
- if you have or have had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels (thromboembolic process)

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- if you have severe diabetes mellitus with blood vessel changes
- if you have sickle cell anaemia
- if you are hypersensitive (allergic) to cyproterone acetate or any of the other ingredients of ANDROCUR.

Warnings and precautions

Take special care with ANDROCUR

Tell your doctor if you suffer from diabetes, since there may be a need to adjust your antidiabetic medication. This condition requires strict supervision during treatment with ANDROCUR (see also “Do not take ANDROCUR”).

Anaemia has been reported during treatment with ANDROCUR. Therefore, your doctor will monitor your red-blood cell count during treatment.

Data from animal studies suggest that high doses of ANDROCUR may decrease the function of the hormone-producing gland attached to the kidney (adrenal gland). Therefore, your doctor may conduct some tests to monitor this effect during treatment with ANDROCUR.

Use of cyproterone acetate has been linked to the development of a generally benign brain tumour (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 notice any symptoms such as change in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headache that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

If you are diagnosed with meningioma, your doctor will stop treatment with ANDROCUR (see section “Do not take ANDROCUR”).

Occasionally, ANDROCUR can lead to a sensation of shortness of breath.

Blood clots (thromboembolic events) have been reported in patients using ANDROCUR, although a direct link has not been established. Patients with history of blood clots or with advance tumours have an increased risk of further suffering blood clots.

Tell your doctor if you have ever had an arterial or venous blood clot, such as a deep vein thrombosis, a clot in the lung (pulmonary embolism), a heart attack (myocardial infarction), or a stroke (cerebrovascular accident).

Tell your doctor if you have ever suffered from any form any of the following as he/she will need to conduct a careful evaluation before deciding to prescribe ANDROCUR:

- A blood circulation disorder (especially blood clots)
- Sickle cell anemia
- Sever diabetes with vascular changes

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Specifically, to be observed by women

Before starting treatment, a thorough medical and gynaecological examination (including the breasts and a cytological smear of the cervix) should be performed and pregnancy must be excluded.

If, during combined treatment with a progestogen-estrogen contraceptive, slight "unscheduled" bleeding occurs during the 3 weeks in which the contraceptive tablets are being taken, tablet-taking should not be interrupted. However, if the bleeding is heavy, you should consult your doctor.

With regard to the necessary additional use of a combined oral contraceptive preparation, attention is also drawn to all the data contained in the package insert for this preparation.

Specifically, to be observed by males

In the indication "reduction of drive in sexual deviations", the drive-reducing effect of ANDROCUR can be diminished under the disinhibitory influence of alcohol.

Children and adolescents

ANDROCUR must not be given before the end of puberty in female children and adolescents, as it may have negative effects on growth and the immature hormonal regulation functions.

ANDROCUR is not recommended for use in male children and adolescents below 18 years of age because safety and efficacy have not been established in this age group.

Other medicines and ANDROCUR

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ANDROCUR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor in particular if you are taking statins (medicines for reducing blood fats), as high doses of ANDROCUR may worsen certain side effects (myopathy or rhabdomyolysis) which may occur during treatment with statins.

Also inform your doctor if you are taking other medicines which affect the liver, such as:

- ketoconazole, itraconazole, clotrimazole (for fungal infection)
- ritonavir (for viral infections)
- rifampicin (for tuberculosis)
- phenytoin (for epilepsy)
- the herbal remedy St. John's wort

High doses of ANDROCUR (100 mg, 3 times per day) may block certain liver enzyme, which may influence the effects of other medicines.

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Pregnancy and breastfeeding and fertility

ANDROCUR must not be used during pregnancy or breastfeeding.

Driving and using machines

ANDROCUR can lead to tiredness and decreased energy and impair your concentration.

ANDROCUR contains

Excipients
Lactose monohydrate
Maize starch
Povidone 25
Colloidal anhydrous silica
Magnesium stearate.

ANDROCUR 50 mg contains 105,5 mg lactose per tablet and ANDROCUR 100 mg contains 184,3 mg lactose per tablet. Patient with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. How to take ANDROCUR

Do not share medicines prescribed for you with others.

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

Take the tablet with some liquid after meals.

If you think that the effect of ANDROCUR is too strong or too weak, talk to your doctor or pharmacist.

Do not take more than the maximum daily dose of 300 mg

Do not change or interrupt the treatment or dosage prescribed by your doctor once you feel an improvement.

Dosage in women

For severe signs of androgenisation

Women of childbearing age

If you are pregnant, you must not take ANDROCUR. Therefore, pregnancy must be excluded before the start of therapy.

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ANDROCUR treatment is started on the 1st day of the menstrual cycle (1st day of bleeding). Only women with an absence of periods (amenorrhea) can start ANDROCUR treatment immediately. In this case the first day of treatment will be considered as the 1st day of the cycle and following recommendations the followed as normal.

Two ANDROCUR 50 mg tablets (= 100 mg) are to be taken twice daily from the 5th to the 14th day of the cycle (i.e. for ten days).

If you are receiving the cyclical combined therapy, you should take the tablets around the same time every day.

Every 28 days (the usual duration of a menstrual cycle), after the first cycle of treatment was started, i.e. on the same day of the week, the next cycle of treatment is started, regardless of whether bleeding has stopped or not.

Seven inactive tablets are taken once daily after 21 days, during which time a withdrawal bleeding occurs. Exactly 4 weeks after the first cycle of treatment was started, exactly on the same day of the week, the next cycle of combined treatment is started, regardless of whether bleeding has stopped or not.

When your doctor notices clinical improvement during the combined treatment with progestogen-estrogen contraceptive, the daily dose of ANDROCUR 50 mg during the first 10 days of the combined treatment with a combined oral contraceptive can be reduced to one or half a tablet of ANDROCUR 50 mg.

Post-menopausal or hysterectomised patients

The usual dose is one to half a tablet ANDROCUR 50 mg once daily for 21 days, followed by a seven-day tablet-free interval. If you think the effect of ANDROCUR is too strong or too weak, talk to your doctor or pharmacist.

Dosage in males

Reduction of drive in sexual deviations

The individual dosage will be determined by the doctor. The tablets are to be taken with some liquid after meals. The usual dose is 1 tablet ANDROCUR twice daily. Once the desired effect is achieved, your dose may be gradually lowered.

To stabilise the therapeutic effect, it is necessary to take ANDROCUR over a protracted period of time, if possible, with the simultaneous use of psychotherapeutic measures.

Antiandrogen treatment in inoperable carcinoma of the prostate

100 mg twice to three times daily (= 200-300 mg per day).

The tablets are to be taken with some liquid after the meals.

The treatment and dosage prescribed by the doctor should not be changed or interrupted after improvement or remissions have occurred.

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To reduce the initial increase of male sex hormones in treatment with GnRH agonists:

100 mg twice daily (= 200 mg per day) alone for 5 - 7 days, followed by 100 mg twice daily (= 200 mg per day) for 3 - 4 weeks together with a GnRH agonist.

To treat hot flushes in patients under treatment with GnRH analogues or whose testicles have been removed (orchidectomy):

100 mg once to twice daily (= 100-200 mg per day).

If you take more ANDROCUR than you should

Please consult your doctor or pharmacist in the case of accidental overdose. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take ANDROCUR

Missed tablets in women

If you receive the cyclical combined therapy, you should keep to a particular time of the day for taking the combined oral contraceptive (together with ANDROCUR). If you forget to take the combined oral contraceptive at the usual time, you must take it within the next 12 hours at the latest. If more than 12 hours elapse from the time that you normally take your combined oral contraceptive tablet, contraceptive protection may be reduced in this cycle. If bleeding fails to occur after this cycle, pregnancy must be excluded before tablet-taking is resumed.

Do not take the missed ANDROCUR tablet (do not take a double dose to make up for the missed tablet). Continue taking the tablet at the regular time together with the progestogen-estrogen contraceptive.

Missed tablets in males

Do not take the missed ANDROCUR tablet (do not take a double dose to make up for the missed tablet). Continue taking the tablets at the regular time.

If you stop taking ANDROCUR

The original conditions for which ANDROCUR was prescribed by your doctor may worsen. Do not stop taking ANDROCUR unless your doctor has told you to do so. If you want to stop taking ANDROCUR, you should discuss this with your doctor first.

IF YOU HAVE ANY FURTHER QUESTIONS ON THE USE OF THIS MEDICINE PRODUCT, ASK YOUR DOCTOR OR PHARMACIST

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4. Possible side effects

ANDROCUR can have side effects.

Not all side effects reported for ANDROCUR are included in this leaflet.

Should your general health worsen while taking ANDROCUR, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Generally feeling unwell, fever, nausea, vomiting, loss of appetite, itching all over your body, yellowing of your skin and eyes, light coloured bowel movements, dark coloured urine. These symptoms could be signs of liver toxicity, including inflammation of the liver (hepatitis) or liver failure.
- Unusual upper abdominal pains which do not disappear spontaneously within a short time. These symptoms could be signs of benign or malignant liver tumours which may lead to life-threatening internal bleeding (intra-abdominal haemorrhage).
- Swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak. These symptoms could be signs of formation of blood clots (thromboembolic events).

The most serious undesirable effects associated with the use of ANDROCUR are hepatic toxicity, benign and malignant liver tumours which may lead to intra-abdominal hemorrhage and thromboembolic events.

It is very common to notice decreased libido (sexual desire), erectile dysfunction (inability to achieve or maintain an erection) and reversible inhibition of sperm formation in men and inhibition of ovulation in women.

Common side effects are: gynaecomastia (swelling of the breast gland - in men), fatigue, hot flushes (in men) and sweating (in men).

The less common side effect is rash.

Rarely, you may experience conditions relating to thrombosis (the formation of a blood clot) in the blood vessels (thromboembolic process), hypersensitivity and an increase in sexual desire (in women).

Side effects that may occur with unknown frequency in women are benign and malignant liver tumours, benign brain tumours (meningiomas), allergic reaction (hypersensitivity), weight gain, weight loss, depressed mood, temporary restlessness, reduced sexual drive (decreased libido), increased sexual drive (increased libido), formation of blood clots (thromboembolic events – see section “Take special care with ANDROCUR”), shortness of breath, internal bleeding (intra-abdominal haemorrhage), liver toxicity, including jaundice, inflammation of the liver (hepatitis), liver failure, rash, inhibited ovulation, breast tenderness, spotting, tiredness, fatigue, osteoporosis, anaemia

Under treatment with ANDROCUR, sexual drive and potency are reduced, and the function of the testicles is inhibited. These changes are reversible after ANDROCUR treatment has been discontinued.

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Over the course of several weeks, ANDROCUR inhibits the formation of sperms (spermatogenesis) as a result of the antiandrogenic and antigonadotropic actions. Spermatogenesis recovers gradually within a few months after ANDROCUR treatment has been discontinued.

ANDROCUR may lead to swelling of the breast gland (so-called gynaecomastia, sometimes combined with tenderness to touch of the mamillae) which usually regresses after ANDROCUR treatment has been discontinued.

As with other antiandrogenic treatment, long-term use of ANDROCUR may lead to osteoporosis. Benign brain tumours (meningiomas) have been reported in association with long-term use (several years) of ANDROCUR doses of 25 mg and above (see section “Do not take ANDROCUR” and “Take special care with ANDROCUR”)

Ovulation is inhibited under the combined treatment with progestogen-estrogen contraceptives, so that a state of infertility exists.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ANDROCUR.

5. How to store ANDROCUR

Store at or below 30 °C. Keep blister strips in the original carton until use.
Do not use ANDROCUR after the expiry date which is stated on the carton and on each blister.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

6. Contents of the pack and other information

What ANDROCUR contains

ANDROCUR 50 mg tablets: The active substance is cyproterone acetate (50 mg).
The other ingredients are lactose monohydrate, magnesium stearate, maize starch, povidone 25, colloidal anhydrous silica.

ANDROCUR 100 mg tablets: The active substance is cyproterone acetate (100 mg).
The other ingredients are lactose monohydrate, magnesium stearate, maize starch, povidone 25.

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What ANDROCUR looks like and contents of the pack

ANDROCUR 50 mg tablets: White to faintly yellowish, round, scored on one side, with an embossed “BV” in a regular hexagon on the other side. The tablet can be divided into equal halves.

Cartons containing amber bottles of 20 or 50 tablets or 2 or 5 transparent PVC/aluminium blisters with 10 tablets per blister.

ANDROCUR 100 mg tablets: White to faintly yellowish tablets, scored on one side, with “LA” embossed on both sides of the score and a regular hexagon on the other side. The tablet can be divided into equal halves.

Cartons containing 6 or 12 transparent PVC/aluminium blisters with 10 tablets per blister.

Holder of Certificate of Registration and Manufacturer

Bayer (Pty) Ltd
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1609

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