

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: Androcur 10 mg
DOSAGE FORM: Tablet
STRENGTHS: 10, 0 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ANDROCUR 10 mg tablets cyproterone acetate

Contains sugar – 59,9 mg lactose per tablet

Read this leaflet carefully before you start taking ANDROCUR 10 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ANDROCUR 10 mg 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 10 mg is and what it is used for
2. What you need to know before you take Androcur 10mg
3. How to take ANDROCUR 10 mg
4. Possible side effects
5. Contents of the pack and other information

1. WHAT ANDROCUR 10 mg IS AND WHAT IT IS USED FOR:

ANDROCUR 10 mg is a hormone preparation that blocks the effect of androgens, which are sex hormones produced mainly in males but also – to a lesser extent – in females. The active substance is cyproterone acetate.

In addition to ANDROCUR 10 mg, your doctor will prescribe a progestogen-oestrogen contraceptive to provide contraceptive protection and cycle stabilisation. For the duration of ANDROCUR therapy women of child-bearing age must also receive a combination oral contraceptive. During combined treatment ovarian function is blocked. These changes are reversible after stopping treatment.

ANDROCUR 10 mg tablets are used for moderately severe signs of androgenisation, such as:

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

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2. What you need to know before you take ANDROCUR 10mg:

Do not take ANDROCUR 10 mg

Do not take ANDROCUR 10 mg if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to take ANDROCUR 10 mg.

- if you are hypersensitive (allergic) to cyproterone acetate or any of the other ingredients of ANDROCUR 10 mg (listed in section 6)
- if you are pregnant or breastfeeding
- if you have 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 venous 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 your doctor prescribes a progestogen-oestrogen combined oral contraceptive in combination with ANDROCUR 10 mg, you should also pay careful attention to the information contained in the package insert of the combined oral contraceptive.

Warnings and precautions

ANDROCUR 10 mg must not be given before the end of puberty in female children and adolescents, as it may have a negative effect on growth and the immature hormonal regulation functions.

Tell your doctor if you suffer from diabetes, since he/she may need to adjust your antidiabetic medication. This requires strict supervision during treatment with ANDROCUR 10 mg (see the “Do not take ANDROCUR 10 mg” section).

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-oestrogen contraceptive, slight "unscheduled" bleeding (spotting) 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.

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Other medicines and ANDROCUR 10mg

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ANDROCUR 10 mg with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist, or other healthcare professional, for advice.

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

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

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

ANDROCUR 30mg with food and drinks

Not Applicable

Pregnancy and Breastfeeding

ANDROCUR 10 mg must not be used during pregnancy or breastfeeding.

If you are pregnant or breastfeeding your baby while taking ANDROCUR 10 mg, please consult your doctor, pharmacist, or other health care professional for advice.

Driving and using machines

Not Applicable

ANDROCUR 10 mg contains:

ANDROCUR 10 mg contains 59,9 mg lactose per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ANDROCUR 10 mg.

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3. How to take ANDROCUR 10 mg:

Do not share ANDROCUR 10 mg prescribed for you with any other person.

Always take ANDROCUR 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 10 mg per day

Your doctor will tell you how long your treatment with ANDROCUR 10 mg will last. Do not stop treatment early because the length of treatment is determined by the severity symptoms you have and how long they respond to treatment. If you have the impression that the effect of ANDROCUR 10 mg is too strong or too weak, tell your doctor or pharmacist.

If you are pregnant, you must not take ANDROCUR 10 mg. Therefore, pregnancy must be excluded before the start of therapy.

For the duration of ANDROCUR 10 mg therapy a combined oral contraceptive must be taken. This will provide you with the necessary contraceptive protection and will stabilise the menstrual cycle. You must strictly follow the dosage and directions for use as described in the package insert of the combined oral contraceptive.

Prior to starting ANDROCUR 10 mg treatment it is always necessary for you to receive one complete cycle of a combined oral contraceptive.

You should use extra non-hormonal contraceptive methods (with the exception of the rhythm and temperature methods) during the first 3 weeks of the first pack of the combined oral contraceptive. This menstrual cycle may be shorter than 4 weeks. Further cycles should then be regular.

In the second pack of the combined oral contraceptive, which starts the very next day after completion of the first pack of the combined oral contraceptive, ANDROCUR 10 mg treatment is started on the 5th day of this menstrual cycle (1st day of bleeding = 1st day of the menstrual cycle).

Take the first ANDROCUR 10 mg tablet from the memo-pack out of one of the blisters marked with the corresponding day of the week (for example "Mon" for Monday) and swallow it whole with some liquid. It does not matter at what time of the day you take the tablet, but once you have selected a particular time - preferably after your breakfast or evening meal – you should keep to it.

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

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From now on you must take one ANDROCUR 10 mg tablet every day in the direction indicated by the arrows on the pack (altogether 14 tablets) and as the last tablet of the ANDROCUR 10 mg treatment, the one from the section marked with number "15".

Every 28 days (the usual duration of a menstrual cycle), the above dosage regimen is to be followed.

Missed bleeding

If, in rare cases, bleeding does not occur, tablet-taking must be temporarily stopped and you must consult the doctor in order to exclude pregnancy before tablet-taking is started again.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ANDROCUR 10 mg

Do not take the missed ANDROCUR 10 mg tablet (do not take a double dose to make up for the missed tablet). Continue taking ANDROCUR 10 mg at the regular time together with the combined oral contraceptive.

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 10 mg).

Pay attention to the special notes on contraceptive reliability and to the missed pill recommendations in the product information of the combined oral contraceptive. If bleeding does not occur after this cycle, pregnancy must be excluded before tablet-taking is resumed.

If you stop taking ANDROCUR 10 mg

The original conditions for which ANDROCUR 10 mg was prescribed by your doctor may worsen. Do not stop taking ANDROCUR 10 mg unless your doctor has told you to do so. If you want to stop using ANDROCUR 10 mg, you should discuss this with your doctor first.

4. Possible side effects:

Androcur 10 mg can have side effects

Not all side effects reported for ANDROCUR 10 mg are included in this leaflet. Should your general health worsen while taking ANDROCUR 10 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

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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 movement, dark coloured urine. These symptoms could be signs of liver toxicity, including inflammation of the liver (hepatitis).
- Disturbances of liver function, some of them severe (jaundice, inflammation of the liver [hepatitis]) have been observed in patients treated with ANDROCUR 10 mg. The disturbances of liver function are dose-related and usually develop several months after treatment has begun. Therefore, your doctor will monitor your liver function before treatment and during treatment, especially if there are any symptoms or signs suggestive of liver toxicity. If liver toxicity is confirmed, your doctor will stop treatment with ANDROCUR 10 mg.
- Unusual upper abdominal pains which do not disappear spontaneously within a short time.

Side effects that may occur with unknown frequency

- Benign and malignant liver tumours
- allergic reaction (hypersensitivity)
- weight gain
- weight loss
- liver function abnormal (hepatic function abnormal)
- jaundice
- inflammation of the liver (hepatitis)
- depressed mood
- reduced sexual drive (decreased libido)
- increased sexual drive (increased libido)
- internal bleeding (intra-abdominal haemorrhage)
- rash
- inhibited ovulation
- breast tenderness
- spotting

Ovulation is inhibited under the combined treatment with a contraceptive, so that a state of infertility exists.

If your doctor prescribes a combined oral contraceptive in combination with ANDROCUR 10 mg, you should also pay attention to the special notes on side effects contained in the product information of this combined oral contraceptive.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 10 mg.

5. How to store ANDROCUR 10 mg

Store at or below 30 °C. Keep blister strip in the original carton until use.
Do not use ANDROCUR 10 mg 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 REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

ANDROCUR 10 mg tablets contain cyproterone acetate 10 mg. Contains lactose.

The other ingredients are lactose monohydrate, maize starch, povidone 25000, colloidal anhydrous silica, magnesium stearate.

What ANDROCUR 10mg looks like and contents of the pack

White to faintly yellowish tablets, scored on the one side, with an embossed BW” in a regular hexagon on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Transparent PVC and aluminium blister strip memo-pack containing 15 tablets

Holder of certificate of registration

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