



Androcur® 10 mg

tablets

Active substance: Cyproterone acetate

Bayer Schering Pharma

Package leaflet: Information for the user

Androcur 10 mg tablets

Active substance: Cyproterone acetate

This is a medicament

- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Read all of this leaflet carefully before you start taking this medicine.

- ▶ Keep this leaflet. You may need to read it again.
- ▶ If you have further questions, ask your doctor or pharmacist.
- ▶ This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- ▶ 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.

1. What Androcur 10 mg is and what it is used for
2. Before you take Androcur 10 mg
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1. WHAT ANDROCUR 10 MG IS AND WHAT IT IS USED FOR

Androcur 10 mg is an anti-androgen.

The active substance of Androcur 10 mg inhibits the effect of male hormones (androgens), that are also formed - to a lesser extent - in the female organism.

Androcur 10 mg is used for treating pronounced signs of virilisation in women, which make hormone therapy necessary:

- ▶ severe forms of acne, when it is accompanied by inflammation or the formation of nodes (Acne papulopustulosa, Acne nodulocystica) or if there is a risk of scarring,
- ▶ moderately severe to severe forms of unnaturally increased growth of facial and body hair (hirsutism),
- ▶ moderately severe to severe forms of androgen-dependent baldness (androgenetic alopecia),

when cyproterone acetate has not proved to be effective from a medical point of view at a lower dose as part of a low-dose cyproterone acetate-oestrogen combination 2 mg/0.030 mg or 2 mg/0.035 mg (combined oral contraceptive 'pill') or when another anti-androgen treatment has not been effective.

When treating acne, the physician should weigh hormone treatment against systemic antibiotic therapy.

2. BEFORE YOU TAKE ANDROCUR 10 MG

Do not take Androcur 10 mg

- ▶ if you are hypersensitive (allergic) to cyproterone acetate or one of the other components of Androcur 10 mg.
- ▶ in the event of liver diseases (including elimination disorders, such as Dubin-Johnson syndrome and Rotor syndrome),
- ▶ if you have had or now have liver tumours,
- ▶ if you have known or suspected malignant diseases,
- ▶ if you have been diagnosed with a meningioma (a generally benign tumour of the meninges). Ask your doctor, if you are in doubt.
- ▶ in the event of severe chronic depression,
- ▶ if you have had or now have diseases associated with blood clots (thrombosis) in veins and/or arteries (particularly stroke, cardiac infarction),
- ▶ if you have severe sugar diabetes (Diabetes mellitus) with vascular changes,
- ▶ in the event of changed red blood cells (sickle-cell anaemia),
- ▶ during pregnancy,
- ▶ whilst breast-feeding,
- ▶ if you experience bleeding from the vagina, the cause of which has not been determined by your doctor,
- ▶ if you have had jaundice (idiopathic jaundice of pregnancy), continuous itching (pruritus of pregnancy) and/or bullous eruptions (Pemphigoid gestationis) during an earlier pregnancy.

Heed the contraindications and reasons to stop taking the oestrogen or progestogen-oestrogen combination (oral contraceptive 'pill'), that are listed in their respective package leaflets.

Take special care with Androcur 10 mg:

General

Before you start use, you have to have a thorough general medical as well as a gynaecological examination. Pregnancy has to be ruled out, since taking Androcur 10 mg during pregnancy could cause feminisation signs in a male newborn.

Androcur 10 mg has to be combined with a suitable oestrogen or a suitable progestogen-oestrogen combination (oral contraceptive 'pill') in sexually mature women.

This is the only possibility of avoiding menstrual cycle disturbances and irregular bleeding and attaining the necessary contraceptive protection. Although cyproterone acetate (the active ingredient of Androcur 10 mg) also has a contraceptive effect in combination with an oestrogen or a suitable cyproterone acetate-oestrogen combination contraceptive, it should not be used exclusively for contraception but only used in women who have to be treated for their androgen-dependent skin disorders (see also section 1, 'What Androcur 10 mg is and what it is used for'). Women

who are being treated with cyproterone acetate in combination with an oestrogen and/or with a suitable oestrogen-progestogen combination, should not take any additional oral contraceptive ('pill') during this treatment. Regular intake has to be observed in order to achieve contraceptive protection.

How to react to unexpected bleeding

If there is a slight 'unscheduled' bleed during the three weeks of taking the combination, do not interrupt using the product; however, you have to see your doctor, if there is heavy bleeding.

What to do, when you miss a period

In the exceptional case that you do not have a bleed within the 7-day tablet-free interval, you do have to discontinue treatment and inform your doctor. You may not continue taking the tablets until your doctor has ruled out pregnancy with certainty.

Liver

Please, inform your doctor immediately, if you experience any of the following symptoms.

- ▶ General malaise, fever, nausea, vomiting, lack of appetite, itching over your entire body, jaundice of your skin and eyes, light-coloured stool, dark-coloured urine. These symptoms may be signs of liver damage, including liver inflammation (hepatitis).
- ▶ Liver-function disorders, some severe (jaundice, hepatitis [liver inflammation]), have been observed in patients who were treated with Androcur 10 mg. Liver-function disorders are dose dependent and generally develop over several months after the start of treatment. This is why your doctor will check your liver function prior to the start of treatment and at regular intervals during treatment, particularly if there are any symptoms or signs, which suggest liver damage. If the suspicion of liver damage is verified, your doctor will discontinue treatment with Androcur 10 mg.
- ▶ Unusual pain in the epigastric region, which does not go away on its own within a short time. This pain could be an indication of benign or malignant liver tumours, which can result in life-threatening intra-abdominal haemorrhage.

Sugar diabetes (Diabetes mellitus)

Please, inform your doctor if you suffer from diabetes (Diabetes mellitus), since a dose adjustment for your diabetes medication may be necessary. Therefore, sugar diabetes has to be carefully monitored during treatment with Androcur 10 mg (see also section 2, 'Before You Take Androcur 10 mg')

Taking Androcur 10 mg with other medicines:

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, even those not prescribed.

This is particularly important with medicinal products, which contain:

- ▶ ketoconazole, itraconazole, clotrimazole (to fight fungal infections),
- ▶ ritonavir (antiviral),
- ▶ rifampicin (for the treatment of tuberculosis),
- ▶ phenytoin (to treat epilepsy);

and products with St. John's wort, since they can affect the concentration of the active substance, cyproterone acetate, in the body.

Please note that this information can also apply to medicines that you have taken recently.

Pregnancy and breast-feeding

Do not use Androcur 10 mg during pregnancy and whilst breast-feeding. Ask your doctor or pharmacist for advice before taking/using any medicine.

Driving and using machines.

No investigations have been conducted concerning the effects on the ability to drive and use machines.

Important information about some of the ingredients of Androcur 10 mg:

This medicinal product contains lactose. Therefore, please take Androcur 10 mg only after consultation with your doctor, if you know that you suffer from an intolerance of certain sugars.

3. HOW TO TAKE ANDROCUR 10 MG

Androcur 10 mg tablets are for oral use.

Always take Androcur 10 mg exactly according to your doctor's instructions. You should check with your doctor or pharmacist if you are not sure.

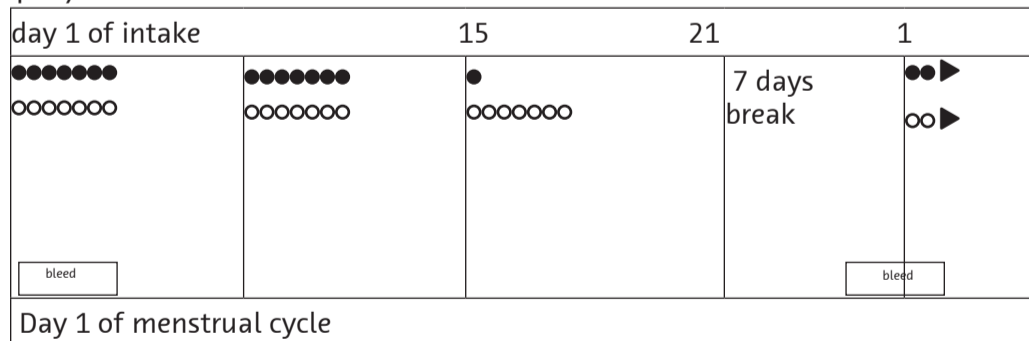
How and when to take Androcur 10 mg

You should take the tablets whole (do not chew) with sufficient liquid (preferably with a glass of drinking water).

The usual dose for a combination therapy with an oestrogen or a progestogen-oestrogen combination is:

Take 1 Androcur 10 mg tablet daily from day 1 to day 15 of the combination therapy.

Additionally, from day 1 to day 21, a suitable oestrogen or a suitable progestogen-oestrogen combinations has to be taken (oral contraceptive 'pill').



- 1 tablet Androcur 10 mg

- 1 coated tablet of the oestrogen or of the progestogen-oestrogen combination used (oral contraceptive 'pill')

You should start taking both products on day 1 of your cycle (day 1 of menstruation). Only women, who do not menstruate, begin immediately with the therapy prescribed by the doctor; in this case, consider day 1 of intake as day 1 of menstruation and calculate further according to the recommendations.

Remove the first Androcur 10 mg tablet from the field of the calendar pack, which corresponds to the day of the week you start the course (e.g. 'Mo' for Monday), and swallow it whole (do not chew). The time of day you take the product is not important; however, you should remain with that time, once you have chosen it.

Now, take one further tablet each day in direction of the arrow (14 altogether) and end with the tablet from the field marked '15'. For a further 6 days, only take the oestrogen or the progestogen-oestrogen combination (oral contraceptive 'pill'), whichever is being used. Afterwards, stop taking the tablets for 7 days, during which time there will be bleeding.

Four weeks after having started taking the tablets, i.e. on the same day of the week, the next combined treatment is started, irrespective of whether the bleeding has already stopped or is still ongoing.

Length of time for using Androcur 10 mg

Your doctor will determine the length of treatment depending upon the type and severity of the pathological signs of virilisation and their

response to treatment.

Therapy has to last for several months.

If there has been a lack of success or only insufficient success in treating

- ▶ severe acne for a period of six months or
- ▶ alopecia and hirsutism after at least 12 months of therapy,

your doctor may consider increasing the dose of cyproterone acetate in combination with an oestrogen or a suitable progestogen-oestrogen combination. When treatment has been adequately successful, treatment may be continued with a low-dose cyproterone acetate-oestrogen combination or an anti-androgen sex steroid. You should also heed any further guidance provided in the package leaflet of the oestrogen or of the suitable progestogen-oestrogen combination (oral contraceptive 'pill'), whichever you used.

Additional information for special populations

Children and adolescents

Androcur 10 mg may be used only after completion of puberty.

Before the end of puberty, an adverse effect of Androcur 10 mg on height (growth in length) cannot be completely ruled out.

There are no data, which require a dosage adjustment.

The safety and efficacy of Androcur in children and adolescents under 18 years has not been established in clinical trials.

Elderly patients (65 years or older)

Androcur 10 mg is only indicated for women of childbearing potential.

Patients with liver disease

Do not take Androcur 10 mg, if you suffer from liver disease (see also in section 2, 'Do not take Androcur 10 mg').

Patients with renal impairment

There have been no studies carried out on the pharmacokinetics (absorption, distribution, degradation and excretion) of Androcur 10 mg in patients with impaired renal function.

If you take more Androcur 10 mg than you should

There are no indications pointing toward serious adverse health effects resulting from an overdose of Androcur 10 mg.

If you forget to take Androcur 10 mg:

If you forgot to take Androcur 10 mg at your usual time, you should continue the combination treatment on time, leaving out the forgotten tablet. Do not take the forgotten tablet(s).

The missed dose of Androcur 10 mg can result in reduced efficacy and intermenstrual bleeding.

If you forgot to take a coated tablet of the progestogen-oestrogen combination (oral contraceptive 'pill') you should take it at the latest within 12 hours of your usual time, since otherwise, its contraceptive effect is jeopardised. Please, heed the advice and recommendations contained in the package leaflet (in particular with regard to the contraceptive effect in the event of missing doses) of the oestrogen or the progestogen-oestrogen combination (oral contraceptive 'pill'), whichever is being used.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Androcur 10 mg can cause side effects, but not everyone treated will have them.

The most commonly reported side effects of patients taking Androcur 10 mg, are intermenstrual bleeding, weight gain and depression.

The most serious adverse drug reactions involved benign and malignant liver tumours, which may cause life-threatening intra-abdominal haemorrhage.

Please, inform your doctor immediately, if you experience any of the following symptoms.

- ▶ General malaise, fever, nausea, vomiting, lack of appetite, itching over your entire body, jaundice of your skin and eyes, light-coloured stool, dark-coloured urine. These symptoms may be signs of liver damage, including liver inflammation (hepatitis).
- ▶ Liver-function disorders, some severe (jaundice, hepatitis [liver inflammation]), have been observed in patients who were treated with Androcur 10 mg. Liver-function disorders are dose dependent and generally develop over several months after the start of treatment. This is why your doctor will check your liver function prior to the start of treatment and at regular intervals during treatment, particularly if there are any symptoms or signs, which suggest liver damage. If the suspicion of liver damage is verified, your doctor will discontinue treatment with Androcur 10 mg.
- ▶ Unusual pain in the epigastric region, which does not go away on its own within a short time. This pain could be an indication of benign or malignant liver tumours, which can result in life-threatening intra-abdominal haemorrhage.

The following side effects have been reported in connection with Androcur 10 mg. Their frequency cannot be estimated from the available data.

Neoplasms, benign, malignant and unspecified (incl. cysts and polyps): Benign and malignant liver tumours*.

Immune system disorders: Allergic reactions (hypersensitivity reactions).

Metabolism and nutrition disorders: Weight gain, weight loss, rise in blood sugar in diabetics

Hepatobiliary disorders: Liver-function disorders, jaundice, hepatitis (liver inflammation).

Psychiatric disorders: Depression, decrease in sex drive (libido), increase in sex drive (libido)

Gastrointestinal disorders: intra-abdominal haemorrhage*.

Skin and subcutaneous tissue disorders: Skin reactions.

Reproductive system and breast disorders: Pain, breast tenderness or breast enlargement, in particular at the start of treatment, irregular or absent menstrual bleeding, spotting*.

* For further information, also see section 2, 'Before you take Androcur 10 mg'

Take special care with Androcur 10 mg:

The occurrence of meningioma (generally benign tumours of the meninges) has been reported in association with prolonged use (years) of Androcur 10 mg in doses of 25 mg/day and more. Stomach complaints and nausea have been commonly reported in connection with medicinal products, which contain cyproterone acetate, the active ingredient of Androcur 10 mg.

Although cyproterone acetate (the active ingredient of Androcur 10 mg) also has a contraceptive effect in combination with an oestrogen or a suitable cyproterone acetate-oestrogen combination, it should not be used exclusively for contraception but only used in women who have to be treated for their androgen-dependent skin disorders (see also: 'What Androcur 10 mg is and what it is used for'). Women who are being treated with cyproterone acetate in combination with an oestrogen or with a suitable oestrogen-progestogen combination, should not take any additional oral contraceptive ('pill') during this treatment. Regular intake has to be observed in order to achieve contraceptive protection.

Furthermore, you should heed all information contained in the section on side effects in the package leaflet of the oestrogen or of the progestogen-oestrogen combination, which you used (oral contraceptive 'pill').

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

5. STORING ANDROCUR 10 MG

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the outer carton.

The expiry date refers to the last day of that month.

store below 30°C.

6. FURTHER INFORMATION

What Androcur 10 mg contains:

The active ingredient is: Cyproterone acetate.

One tablet contains 10 mg cyproterone acetate.

The other ingredients are: lactose monohydrate, colloidal anhydrous silica, magnesium stearate (Ph.Eur.) maize starch, and polyvidone 25,000.

What Androcur 10 mg looks like and contents of the pack:

Androcur 10 mg are white to pale yellow tablets with a decorative score on one side and embossed with 'BW' in a regular hexagon on the other. The decorative score is to break the tablet for ease of swallowing; not to divide the tablet into equal doses.

Androcur 10 mg is available in packs of 15 tablets.

Manufacturer

Schering GmbH und Co. Produktions KG.

Weimar - Germany

a subsidiary of

Bayer Schering Pharma AG, Germany

This leaflet was last approved in May 2012.