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

Androcur-10 is an anti-androgen.

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

Androcur-10 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 the success of cyproterone acetate in small doses (e.g. Diane-35) or other anti-androgenic sex hormones does not seem promising from a medical point of view. When treating acne, the physician should weigh hormone treatment against systemic antibiotic therapy.

2. BEFORE YOU TAKE ANDROCUR-10

Do not take/use Androcur-10,

- if you are hypersensitive (allergic) to cyproterone acetate or one of the other components of Androcur-10,
- if you have 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.
- if you have sever 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 breastfeeding,
- 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 (Herpes gestationis) during an earlier pregnancy.

Heed the contraindications and reasons to stop taking the oestrogen or progestogen-oestrogen combination (e.g. Diane-35), that are listed in their respective package leaflets.

Take special care with Androcur-10

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 during pregnancy could cause feminisation of a male newborn.

Androcur-10 has to be combined with a suitable oestrogen or a suitable progestogen-oestrogen combination (such as Diane-35) in sexually mature women. This is the only possibility of avoiding menstrual cycle disturbances and irregular bleeding and attaining the necessary contraceptive protection.

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

In the exceptional case that you do not have a bleed, you do have to discontinue treatment and inform your doctor.

The liver function has to be monitored during treatment. Please, inform your doctor, if you have sugar diabetes (Diabetes mellitus), since this disease requires careful monitoring.
Taking Androcur-10 with other medicines:
The required amounts of medicines used to treat Diabetes mellitus can change.
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 for medicinal products, that contain ketoconazole, itraconazole, clotrimazole, ritonavir, rifampicin, phenytoin 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 breastfeeding
You may not use Androcur-10 during pregnancy and whilst breastfeeding.
Ask your doctor or pharmacist for advice before taking/using any medicine.

The ability to drive and use machines:
Not applicable

Important information about some of the ingredients of Androcur-10
This medicinal product contains lactose. Therefore, please take Androcur-10 only after consultation with your physician, if you know that you suffer from an intolerance of certain sugars.

3. HOW TO TAKE ANDROCUR-10
Androcur-10 are tablets for oral use.
Always take Androcur-10 exactly according to your doctor’s instructions.
You should check with your doctor or pharmacist if you are unsure.

How and when to use Androcur-10
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 one oestrogen or a progestogen-oestrogen combination is:
Take 1 tablet Androcur-10 daily from day 1 to day 15 of the combination therapy. Additionally from day 1 to day 21, take a suitable oestrogen or a suitable progestogen-oestrogen combinations (such as Diane-35).

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 tablet from that field of the calendar pack, that 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 (e.g. Diane-35) that you are using.
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, start with the next combined treatment, irrespective of whether the bleeding has already stopped or is still ongoing.

Length of time for using Androcur-10
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 has to reassess the treatment approach and consider a higher dosed, combined use of Androcur and a suitable oestrogen or a suitable progestogen-oestrogen combination (such as Diane-35).
When success has been achieved, an attempt should be made to manage with using only Diane-35 or another anti-androgenic sex steroid.

You should also heed any further guidance provided in the package leaflet of the oestrogen you used or of the relevant progestogen-oestrogen combination (e.g. Diane-35).

**If you take more Androcur-10 than you should**
There are no indications pointing toward serious adverse health effects resulting from an overdose of Androcur-10.

Even in the event of an unintentional single intake of several times the therapeutic dosage, an acute risk of poisoning is not likely.

**If you forget to take Androcur-10**
If you forgot to take Androcur-10 at your usual time, you should continue the combination treatment on time, leaving out the forgotten tablet. Do not take the forgotten tablet(s). Having forgotten to take Androcur-10 can result in reduced efficacy and intermenstrual bleeding.

If you forgot to take a coated tablet of the progestogen-oestrogen combination (e.g. Diane-35) you should take it at the latest within 12 hours of your usual time, since otherwise, its contraceptive effect is put into question. For that purpose, please heed the guidance provided in the package leaflet of the oestrogen or of the progestogen-oestrogen combination you used (e.g. Diane-35).

### 4. POSSIBLE SIDE EFFECTS
Like all medicines, Androcur-10 can cause side effects, although not everybody gets them.

The following incidence rating is used to evaluate the frequency of side effects:

| Very common: | more than 1 out of 10 treated |
| Common: | less than 1 out of 10, but more than 1 out of 100 treated |
| Uncommon: | less than 1 out of 100, but more than 1 out of 1,000 treated |
| Rare: | less than 1 out of 1,000, but more than 1 out of 10,000 treated |
| Very rare: | less than 1 out of 10,000 treated, including individual cases |

The occurrence of meningiomas (generally benign tumours of the meninges) have been reported in association with prolonged use (years) of Androcur-10 in dosages of 25 mg/day and more.

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 you used (e.g. Diane-35).

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

### 5. STORING ANDROCUR-10
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 the month indicated.

Store below 30°C.

### 6. FURTHER INFORMATION
What Androcur-10 contains:
The active substance is cyproterone acetate.
1 tablet contains 10 mg cyproterone acetate.
The other constituents are: lactose monohydrate, colloidal anhydrous silica, magnesium stearate (Ph. Eur.) maize starch, and polyvidone 25,000.

**What Androcur-10 looks like and contents of the pack:**
Androcur-10 are white to pale yellow, round tablets, with a decorative score and unilateral embossment with the letters “BW” in a regular hexagon.
Androcur-10 is available in packs of 15 tablets und 3 x 15 tablets.

**Manufacturer**
Schering GmbH und Co. Produktions KG
D-99427 Weimar, Germany
A subsidiary of:
Bayer Schering Pharma AG
D-13342 Berlin, Germany.

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