

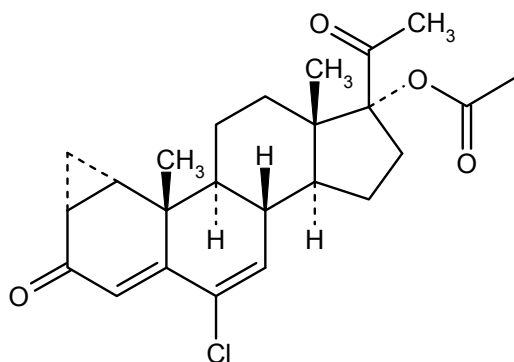
## **ANDROCUR® PRODUCT INFORMATION**

### **NAME OF THE MEDICINE**

Androcur 10mg and Androcur 50mg

Each pack contains tablets containing either 10mg or 50mg cyproterone acetate.

Cyproterone acetate:



Chemical Name: 6-chloro-17 $\alpha$  hydroxy-1 $\alpha$ ,2 $\alpha$ -methylene-pregna-4,6-diene-3,20-dione acetate

Molecular Formula: C<sub>24</sub>H<sub>29</sub>ClO<sub>4</sub>

Molecular Mass: 416.96

CAS No.: 427-51-0

### **DESCRIPTION**

Cyproterone acetate is a white to pale yellow crystalline powder. M.P. 206-213°C. Cyproterone acetate is very soluble in chloroform and dioxane, freely soluble in acetone and benzene, soluble in ethanol, methanol and ethyl acetate, sparingly soluble in solvent hexane, and almost insoluble in water.

### **PHARMACOLOGY**

Androcur is an antiandrogenic hormone preparation.

Cyproterone acetate inhibits competitively the effect of androgens at androgen-dependent target organs, e.g. it shields the prostate from the effect of androgens originating from the gonads and/or the adrenal cortex. Prostatic carcinoma and its metastases are in general androgen-dependent, Androcur therefore exerts a direct antiandrogenic action on the tumour and its metastases.

Cyproterone acetate in addition has a progestogenic action exerting a negative feedback effect centrally on the hypothalamic receptors, so leading to a reduction in gonadotropin release, and hence to diminished production of testicular androgens. Treatment with cyproterone acetate in men results in a reduction of sexual drive and potency and inhibition of gonadal function. These changes are reversible following discontinuation of the therapy.

The antigonadotropic effect of cyproterone acetate is also exerted when the substance is combined with LHRH agonists. The initial increase of testosterone provoked by this substance group is decreased by cyproterone acetate.

In women, hirsutism is diminished, but also androgen-dependent loss of scalp hair and elevated sebaceous gland function are reduced. During the treatment ovarian function is inhibited.

Prolactin levels can increase slightly under higher doses of cyproterone acetate. Studies showed increased prolactin levels up to 20ng/mL (normal range 5-15ng/mL). There are no data for periods longer than 6 months.

## **Pharmacokinetic properties**

### **Absorption**

Following oral administration, cyproterone acetate is completely absorbed over a wide dose range.

The ingestion of 50mg of cyproterone acetate gives maximum serum levels of about 140ng/mL at about 3 hours. Thereafter, drug serum levels declined during a time interval of typically 24 to 120 hours, with a terminal half-life of  $43.9 \pm 12.8$ h. The total clearance of cyproterone acetate from serum was determined to be  $3.5 \pm 1.5$  mL/min/kg. The absolute bioavailability of cyproterone acetate is unknown. Relative bioavailability was calculated, in a study of eight young women, from a dose-corrected comparison of area under the curves of serum levels after 100mg oral and 300mg intramuscular depot administration and was found to be  $80 \pm 30\%$  when averaged over all volunteers (range 23%-119%).

### **Distribution**

The major part of circulating cyproterone acetate is bound to serum albumin. In a study in 15 women receiving 2mg cyproterone acetate in combination with 35µg ethinyloestradiol, the free fraction of cyproterone acetate was about 3.5-4%. Because protein binding is non-specific, changes in SHBG (sex hormone binding globulin) levels do not affect the pharmacokinetics of cyproterone acetate.

### **Metabolism**

Cyproterone acetate is metabolised by various pathways, including hydroxylations and conjugations. The main metabolite in human plasma is the 15β-hydroxy derivative. Some dose parts are excreted unchanged with bile fluid. Phase 1 metabolism of cyproterone acetate is mainly catalysed by the cytochrome P450 enzyme CYP3A4.

### **Elimination**

In a study in 6 women administered a <sup>14</sup>C labelled dose of 2mg cyproterone acetate in combination with 50µg oestrogen, approximately 30% of the label was found in the urine and 58% in the faeces. The renal and biliary excretion was determined to proceed with a half-life of 1.9 days. Metabolites from plasma were eliminated at a similar rate (half-life of 1.7 days).

### **Steady state conditions**

According to the long half-life of the terminal disposition phase from plasma (serum) and the daily intake, an accumulation of cyproterone acetate by a factor of about 3 can be expected in the serum during repeated daily administration.

## INDICATIONS

### WOMEN:

#### **Moderately severe to severe signs of androgenisation**

- moderately severe/severe forms of hirsutism
- moderately severe/severe androgen-dependent loss of scalp hair (moderately severe/severe androgenic alopecia)
- moderately severe/severe forms of acne and/or seborrhoea associated with other features of androgenisation

Cyproterone acetate inhibits the influence of male sex hormones which are also produced by the female. It is thus possible to treat diseases in women caused either by increased production of androgens or a particular sensitivity to these hormones. Hirsutism and alopecia may be expected to recur over a period of time after cessation of treatment.

If Androcur is taken during pregnancy, the properties of the preparation may lead to signs of feminisation in the male foetus. Therefore, in women of childbearing potential, pregnancy must be excluded at the commencement of treatment and ethinyloestradiol taken as well to ensure contraception. This also promotes regular menstruation.

### MEN:

#### **Reduction of drive in sexual deviations**

Androcur reduces the force of the sexual urge in men with sexual deviations. Whilst under treatment the man can control himself better in a predisposing stimulatory situation, but there is no influence on any deviating direction of sexual drive. Abnormal patterns of sexual behaviour require treatment when they are distressing to the patient. A pre-requisite for therapy is the desire by the patient for treatment.

Androcur therapy should be supplemented by psychotherapeutic and sociotherapeutic measures in order to exploit the period of reduced drive for personal and social re-orientation.

#### **Inoperable prostatic carcinoma**

- to suppress "flare" with initial LHRH analogue therapy
- in long term palliative treatment where LHRH analogues or surgery are ineffective, not tolerated, contraindicated or where oral therapy is preferred
- in the treatment of hot flushes in patients treated with LHRH analogues or who have had orchidectomy.

## CONTRAINDICATIONS

### **Contraindications in women**

- Pregnancy
- Lactation
- Liver diseases
- Dubin-Johnson syndrome, Rotor syndrome
- History of jaundice or persistent pruritus during a previous pregnancy
- History of herpes of pregnancy
- Previous or existing liver tumours
- Presence or history of meningioma
- Wasting diseases

- Severe chronic depression
- Previous or existing thromboembolic processes
- Severe diabetes with vascular changes
- Sickle-cell anaemia
- Hypersensitivity to any of the components of Androcur

With regard to the cyclical combined therapy of severe signs of androgenisation, attention is also drawn to the data on contraindications contained in the product information for the progestogen-oestrogen containing preparation used in addition to Androcur.

### **Contraindications in men**

#### Reduction of drive in sexual deviations

- Liver diseases
- Dubin-Johnson syndrome, Rotor syndrome
- Previous or existing liver tumours
- Presence or history of meningioma
- Wasting diseases
- Severe chronic depression
- Previous or existing thromboembolic processes
- Severe diabetes with vascular changes
- Sickle-cell anaemia
- Hypersensitivity to any of the components of Androcur

#### Inoperable carcinoma of the prostate

- Liver diseases
- Dubin-Johnson syndrome, Rotor syndrome
- Previous or existing liver tumours (only if these are not due to metastases from carcinoma of the prostate)
- Presence or history of meningioma
- Wasting diseases (with the exception of inoperable carcinoma of the prostate)
- Severe chronic depression
- Existing thromboembolic processes
- Hypersensitivity to any of the components of Androcur

Androcur should not be given before the conclusion of puberty since an unfavourable influence on longitudinal growth and the still unstabilised axes of endocrine function cannot be ruled out.

### **PRECAUTIONS**

During treatment liver function, adrenocortical function and red blood cell count should be checked regularly.

The long term effects on female fertility are not known with certainty.

In men of procreative age, for whom fertility could be important after conclusion of the medication, it is advisable to make at least one control spermatogram as a precaution before the start of treatment in order to counter any unjustified claims of later infertility as a result of the antiandrogen therapy. Spermatogenesis has taken 3-20 months to return to normal after discontinuing therapy.

## **Liver**

Direct hepatic toxicity, including jaundice, hepatitis and hepatic failure has been observed in patients treated with cyproterone acetate. At dosages of 100mg and above, cases with fatal outcome have been reported. Most reported fatal cases were in men with advanced carcinoma of the prostate. Toxicity is dose-related and develops, usually, several months after treatment has begun. Liver function tests should be performed pre-treatment, at regular intervals during treatment and whenever any symptoms or signs suggestive of hepatotoxicity occur. If hepatotoxicity is confirmed, Androcur should be withdrawn, unless hepatotoxicity can be explained by another cause, e.g. metastatic disease, in which case Androcur should be continued only if the perceived benefit outweighs the risk.

Cases of benign and malignant liver tumours, which may lead to life-threatening intra-abdominal haemorrhage, have been observed after the use of Androcur. If severe upper abdominal complaints, liver enlargement or signs of intra-abdominal haemorrhage occur, a liver tumour should be included in the differential diagnostic considerations.

## **Meningioma**

The occurrence of meningiomas (single and multiple) has been reported in association with long-term use (years) of cyproterone acetate at doses of 25mg/day and above. If a patient treated with Androcur is diagnosed with meningioma, treatment with Androcur must be stopped (see **CONTRAINDICATIONS**).

## **Diabetes**

Strict medical supervision is necessary if the patient suffers from diabetes because the requirement for oral antidiabetics or insulin can change during Androcur treatment (see **CONTRAINDICATIONS**).

## **Shortness of breath**

A sensation of shortness of breath may occur under high-dosed treatment with Androcur. The differential diagnosis in such cases must include the stimulating effect on breathing known for progesterone and synthetic progestogens which is accompanied by hypocapnia and compensated respiratory alkalosis and which is not considered to require treatment.

## **Thromboembolic events**

The occurrence of thromboembolic events has been reported in patients using Androcur although a causal relationship has not been established. Patients with previous arterial or venous thrombotic / thromboembolic events (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction) or with a history of cerebrovascular accidents or with advanced malignancies are at increased risk of further thromboembolic events.

## **Adrenocortical function**

During treatment adrenocortical function should be checked regularly, as preclinical data suggest a possible suppression due to the corticoid-like effect of Androcur with high doses.

## **Anaemia**

Anaemia has been reported during treatment with Androcur. Therefore, the red-blood cell count should be checked regularly during treatment.

## Other conditions

Androcur tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose mal-absorption should not take this medicine.

## Specifically to be observed in women

Before the start of therapy a thorough general medical and gynaecological examination (including the breasts and a cytological smear of the cervix) should be carried out. Serious organic causes of androgenisation, e.g. Cushing's syndrome, ovarian tumours, adrenal carcinoma and adrenogenital syndrome should be excluded. Pregnancy must be excluded at the time of commencing treatment in women of child-bearing potential. If, during the combined treatment, spotting occurs during the 3 weeks in which the tablets are being taken, tablet-taking should not be interrupted. However, if persistent or recurrent bleeding occurs at irregular intervals, a gynaecological examination must be carried out to exclude organic diseases.

With regard to the additional use of a combined oral contraceptive preparation, attention is drawn to all the data contained in the product information for this product.

## Specifically to be observed in men

The sexual drive-reducing effect of Androcur can be diminished under the influence of alcohol.

In patients with inoperable carcinoma of the prostate presenting with a history of thromboembolic processes or suffering from sickle-cell anaemia or from severe diabetes with vascular changes, a careful risk: benefit evaluation must be carried out in each individual case before Androcur is prescribed.

## Use in pregnancy: Category D

The use of Androcur is contraindicated during pregnancy (also see **CONTRAINDICATIONS**).

Administration of cyproterone acetate during the hormone-sensitive differentiation phase of the genital organs (after approx. day 45 of pregnancy) could lead to signs of feminisation in male fetuses.

## Use in lactation

The use of Androcur is contraindicated during lactation as small amounts of cyproterone acetate are excreted in human milk (see **CONTRAINDICATIONS**).

## Carcinogenicity and mutagenicity

Cyproterone acetate was negative in a standard battery of genotoxicity studies. However, further tests showed that cyproterone acetate was capable of producing hepatocyte DNA adducts in rats, dogs and monkeys (and an increase in DNA-repair activity in rats) *in vivo* and also in freshly isolated rat and human liver cells *in vitro*. This DNA-adduct formation occurred at exposures that might be expected to occur in the recommended dose regimens for Androcur. *In vivo* consequences of cyproterone acetate treatment were the increased incidence of focal, possibly pre-neoplastic, liver lesions in which cellular enzymes were altered in female rats, and an increase of mutation frequency in transgenic rats carrying a

bacterial gene as target for mutation. The clinical relevance of these findings presently remains uncertain.

Long-term animal carcinogenicity studies were performed in rats and mice. In one rat study, an increased incidence of hepatomas was reported at oral dose levels of 50mg/kg cyproterone acetate and above. In mouse (and a second rat) carcinogenicity studies, increases in benign proliferative changes (nodular hyperplasia) in liver cells of female mice and male and female rats were reported at oral doses of 2mg/kg. Because of shortcomings in these studies (inadequate pharmacokinetic data and the need to reassess the liver pathology), the carcinogenic potential of cyproterone acetate in animals could not be determined.

Clinical experience and limited epidemiological data available to date do not appear to have supported an increased incidence of hepatic tumours in humans. However, it must be borne in mind that steroidal sex hormones can promote the growth of certain hormone-dependent tissues and tumours.

### **Interactions with other medicines**

The requirement for oral antidiabetics or insulin can change.

Although clinical interaction studies have not been performed, since this drug is metabolized by CYP3A4, it is expected that ketoconazole, itraconazole, clotrimazole, ritonavir and other strong inhibitors of CYP3A4 inhibit the metabolism of cyproterone acetate. On the other hand, inducers of CYP3A4 such as e.g. rifampicin, phenytoin and products containing St. John's wort may reduce the levels of cyproterone acetate.

The risk of statin-associated myopathy or rhabdomyolysis may be increased when those HMGCoA inhibitors (statins), which are primarily metabolised by CYP3A4, are co-administered with high therapeutic cyproterone acetate doses since they share the same metabolic pathway.

Based on *in vitro* CYP450 studies, the recommended clinical doses are likely to inhibit CYP2C8, and an inhibition of the CYP 2C9, 2C19, 3A4, and 2D6 is also possible at high therapeutic cyproterone acetate doses of 3 times 100mg per day.

### **Effects on ability to drive and use machines**

It should be pointed out to patients whose occupation demands great concentration (e.g. road users, machine operators) that Androcur can lead to tiredness and diminished vitality and can impair the ability to concentrate.

## **ADVERSE EFFECTS**

### **Adverse reactions reported in clinical trials**

The following adverse reactions have been reported at the approximate frequencies (not necessarily implicating a causal relationship) indicated below:

Very common	≥ 1/10
Common	≥ 1/100 and <1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

**General**

*Very common:* tiredness, weight increase

*Common:* headache, depressive moods

**Cardiovascular**

*Common:* thrombotic phenomena

**Gastrointestinal**

*Common:* nausea and other gastrointestinal complaints

**Reproductive**

*Very common:* Diminished libido

*Common:* mastodynia, irregular menstrual cycles

**Skin**

*Rare:* rash

The most commonly reported adverse drug reactions (ADRs) in female patients receiving Androcur are spotting, weight increase and depressed mood.

The most frequently observed ADRs in male patients receiving Androcur are decreased libido, erectile dysfunction and reversible inhibition of spermatogenesis.

The most serious ADRs in patients receiving Androcur are hepatic toxicity, benign and malignant liver tumours which may lead to intra-abdominal haemorrhage, and thromboembolic events.

Over the course of several weeks Androcur gradually impairs spermatogenesis as a result of the antiandrogenic and antigonadotropic actions. Spermatogenesis recovers gradually within several months of discontinuing therapy.

In male patients Androcur occasionally leads to gynaecomastia (sometimes combined with tenderness to touch of the breast) which usually regresses after withdrawal of the preparation or reduction of the dose.

As with other antiandrogenic treatments, in male patients long-term androgen deprivation with Androcur may lead to osteoporosis.

In women ovulation is inhibited under the combined treatment so that a state of infertility exists.

A feeling of tension in the breasts may occur.

In individual cases, disturbances of liver function, some of them severe, have been reported with high-dosed Androcur treatment.

Changes in body weight are possible.

Other adverse events reported at a low incidence were dysmenorrhoea, vaginal discharge, skin discolouration, striae.

**Post-marketing information**

The following adverse effects have been reported in users of cyproterone acetate and are based on post-marketing data and cumulative experience with Androcur. The most



appropriate MedDRA term to describe a certain adverse reaction is listed. Synonyms or related conditions are not listed, but should be taken into account as well.

<b>System organ class (MedDRA)</b>	<b>Very common ≥ 1/10</b>	<b>Common ≥ 1/100 and &lt; 1/10</b>	<b>Uncommon ≥ 1/1000 and &lt; 1/100</b>	<b>Rare ≥ 1/10000 and &lt; 1/1000</b>	<b>Very rare &lt; 1/10000</b>
<b>Neoplasms benign and malignant</b>					Benign & malignant liver tumours*
<b>Blood and lymphatic system disorders</b>					
<b>Immune system disorders</b>				Hypersensitivity reaction	
<b>Metabolism and nutrition disorders</b>		Weight increased or Weight decreased			
<b>Psychiatric disorders</b>	Libido decreased (men), Erectile dysfunction	Depressed mood Restlessness (temporary)	Libido decreased (women)	Libido increased (women)	
<b>Skin and subcutaneous tissue disorders</b>			Rash		
<b>Musculoskeletal and connective tissue disorders</b>					Osteoporosis (men)
<b>Hepatobiliary disorders</b>		Hepatic toxicity, including jaundice, hepatitis, hepatic failure*		Increased liver enzymes	Liver function disturbance
<b>Gastrointestinal disorders</b>					Nausea GI complaints
<b>Cardiovascular disorders</b>					Thrombotic phenomena Tachycardia
<b>Reproductive system and breast disorders</b>	Reversible inhibition of spermatogenesis Ovulation inhibited	Gynaecomastia (men) Breast tenderness (women)			Breast pain Irregular menstrual periods Galactorrhoea
<b>General disorders and administration site conditions</b>		Fatigue Hot flushes Sweating			Tiredness Sleep disturbances Headache
<b>Respiratory, thoracic and mediastinal disorders</b>		Shortness of breath*			

\* For further information see **PRECAUTIONS**

† A causal relationship with Androcur has not been established

The ADRs identified only during post-marketing surveillance and for which a frequency could not be estimated are: anaemia\*, meningioma, intra-abdominal haemorrhage\*, rash, menstrual spotting\*, thromboembolic events\*†.

In male patients under treatment with Androcur, sexual drive and potency are reduced and gonadal function is inhibited. These changes are reversible after discontinuation of therapy.

Meningiomas have been reported in association with long-term use (several years) of Androcur doses of 25mg and above (see **CONTRAINDICATIONS** and **PRECAUTIONS**).

## **DOSAGE AND ADMINISTRATION**

Androcur tablets should be taken with some liquid after a meal.

### **WOMEN:**

Pregnant women must not take Androcur. Therefore, pregnancy must be excluded before the start of therapy.

In women of childbearing potential, the treatment is commenced on the 1st day of the cycle (=1st day of bleeding). Only women with amenorrhoea or menstrual bleeding at very irregular intervals can start treatment immediately. In this case the first day of treatment is to be regarded as the 1st day of the cycle and the following recommendations then observed as normal.

For hirsutism secondary to female androgenisation; the usual starting dose should be 1 tablet of Androcur 50mg taken daily for 10 days per month (from the 1st to the 10th day of the cycle). Once a satisfactory response has been attained it is usually possible to reduce the dose further. Doses as low as 10mg a day for 10 days per month have been shown to be adequate for maintenance therapy in this condition.

For other severe signs of androgenisation; 2 tablets of Androcur 50mg are to be taken daily from the 1st to the 10th day of the cycle (= for 10 days).

In addition, these women should receive a progestogen-oestrogen containing preparation, to provide the necessary contraceptive protection and to stabilise the cycle. An appropriate combined oral contraceptive preparation should be commenced on day 1 of the cycle as directed.

Women receiving the cyclical combined therapy should keep to a particular time of the day for tablet-taking. If more than 12 hours elapse from this time, contraceptive protection in this cycle may be reduced. **Attention is drawn to the special notes (especially on contraceptive reliability and to the missed tablet recommendations) in the product information for the combined oral contraceptive preparation being taken in conjunction with Androcur.** If bleeding fails to occur after this cycle, pregnancy must be excluded before tablet-taking is resumed.

Missed Androcur tablets may diminish the therapeutic efficacy and may lead to intermenstrual bleeding. The missed Androcur tablet should be disregarded (no double dose should be taken to make up for the missed tablet) and tablet taking resumed at the regular time together with the combined oral contraceptive preparation.

A withdrawal bleeding usually occurs during the tablet free interval or whilst taking the 7-day placebo tablets. Exactly 4 weeks after the first course of treatment was started, ie. on the same day of the week, the next cyclical course of combined treatment is started, regardless

of whether bleeding has stopped or not. If no bleeding occurs during the tablet free or 7 day placebo tablet interval, the possibility of pregnancy must be excluded before restarting tablet taking.

Following clinical improvement, the daily dose of Androcur 50mg may be reduced to 1 or 1/2 tablet during the 10 days on which it is given in each treatment cycle. The dose regimen for the combined oral contraceptive preparation remains unchanged. If improvement is maintained over a further few months Androcur 10mg daily from the 1st to the 15th day of the cycle (= 15 days) may be sufficient.

In postmenopausal or hysterectomised patients Androcur may be administered alone. According to the severity of the complaints, the average dose should be 1/2 to 1 tablet Androcur 50mg once daily for 21 days, followed by a 7-day tablet-free interval.

The length of treatment depends on the severity of the pathological signs of androgenisation and response to treatment. Treatment is usually carried out over several months initially. Acne and seborrhoea usually respond sooner than hirsutism or alopecia. Hirsutism and alopecia are likely to recur when treatment is stopped.

#### **MEN:**

The maximum daily dose is 300mg.

#### **Reduction of drive in sexual deviations**

The individual dose will be determined by the response. Generally, treatment is started with one 50mg tablet twice daily. It may be necessary to increase the dose to two 50mg tablets twice daily, or even two 50mg tablets three times daily for a short period of time. If a satisfactory result is achieved, the therapeutic effect should be maintained with the lowest possible dose. Quite often 1/2 tablet twice daily is sufficient. When establishing the maintenance dose or when discontinuing the preparation, the dosage should not be reduced abruptly, but gradually. To this end, the daily dose should be reduced by 1 tablet, or better 1/2 tablet, at intervals of several weeks.

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.

#### **Inoperable prostatic carcinoma**

#### **To reduce the initial increase of male sex hormones ('flare') in treatment with LH-RH agonists**

Initially 100mg (2 tablets Androcur 50mg) twice daily alone for 5-7 days, then 100mg (2 tablets Androcur 50mg) twice daily for 3-4 weeks together with an LHRH agonist in the dosage recommended by the manufacturer.

#### **In long term palliative treatment of advanced prostate cancer in patients who have not had an orchiectomy**

100mg (2 tablets Androcur 50mg) two to three times daily. Treatment should not be interrupted nor the dosage reduced after improvement or remissions have occurred.

**To treat hot flushes in patients under treatment with LHRH analogues or who have had orchiectomy**

50mg once to three times daily with upward titration to 100mg three times daily if necessary.

**Children and adolescents**

Androcur is not recommended for use in female patients before conclusion of puberty. There are no data suggesting the need for dosage adjustment in female patients who have completed puberty.

Androcur is not recommended for use in male children and adolescents below 18 years of age due to a lack of data on safety and efficacy.

Androcur must not be given before the conclusion of puberty since an unfavourable influence on longitudinal growth and the still unstabilised axes of endocrine function cannot be ruled out.

**Use in the elderly**

There are no data suggesting the need for dosage adjustment in elderly patients.

**Patients with hepatic impairment**

The use of Androcur is contraindicated in patients with liver diseases.

**Patients with renal impairment**

There are no data suggesting the need for dosage adjustment in patients with renal impairment.

**OVERDOSAGE**

There is no clinical experience in overdose. Assessment and symptomatic treatment should be initiated as required.

In cases of overdose, it is advisable to contact the Poisons Information Centre (131126) for recommendations on the management and treatment of overdose.

**PRESENTATION AND STORAGE CONDITIONS**

Androcur 50mg - bottles\* or blisters of 20 and 50 round, white, scored tablets

Androcur 10mg\* - memo packs of 15 round, white, scored tablets

Presentations marked \* are not marketed in Australia

PBS availability (Authority Required):

Tablets 50mg - Qty. 20 Rpts. 5

Tablets 50mg - Qty. 50 Rpts. 5

Each Androcur 50mg tablet contains 50mg cyproterone acetate

Each Androcur 10mg tablet contains 10mg cyproterone acetate

Store Androcur tablets below 30°C.

**Excipients**

lactose  
maize starch  
povidone  
colloidal anhydrous silica  
magnesium stearate

**NAME AND ADDRESS OF THE SPONSOR**

Bayer Australia Limited  
ABN 22 000 138 714  
875 Pacific Highway  
Pymble, NSW 2073

**POISONS SCHEDULE OF THE MEDICINE**

S4

**DATE OF TGA APPROVAL**

1 December 2008

**Date of most recent amendment:** 9 November 2010

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