

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start using Androcur Depot.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

Androcur Depot 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.

SCHEDULING STATUS**S4****PROPRIETARY NAME AND DOSAGE FORM**

Androcur Depot Solution for injection

WHAT ANDROCUR DEPOT CONTAINS

One 3 ml ampoule Androcur Depot contains cyproterone acetate 300 mg in oily solution. The other ingredients are castor oil for injection, benzyl benzoate.

WHAT ANDROCUR DEPOT IS AND WHAT IT IS USED FOR

Androcur Depot is a hormone preparation acting against male sex hormones. It inhibits the influence of male sex hormones (androgens) at their target organs, thus counteracting androgen-dependent pathological processes.

Androcur Depot shields androgen-dependent target organs, e.g. the prostate, from the effect of androgens originating from the testicles and/or the adrenal cortex (a hormone producing gland attached to the kidneys).

Androcur Depot also diminishes the testosterone concentration in the blood which has an additional therapeutic effect.

Under treatment with Androcur Depot, sexual drive and potency are reduced, and the function of the testicles is inhibited.

Androcur Depot is used for 1) Reduction of drive in sexual deviations in males and 2) Inoperable carcinoma of the prostate.

DO NOT USE ANDROCUR DEPOT

Do not use Androcur Depot if you have any of the conditions listed below. If any of these apply to you, tell your doctor before using Androcur Depot.

- 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 have had a benign or malignant liver tumour (only if these are not due to metastases from carcinoma of the prostate).
- 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 have 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)
- 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 Depot.

BEFORE YOU USE ANDROCUR DEPOT**Take special care with Androcur Depot:**

- In the indication “reduction of drive in sexual deviations”, the drive-reducing effect of Androcur Depot can be diminished under the disinhibitory influence of alcohol.
- Androcur Depot should not be given before the conclusion of puberty, since an unfavourable influence on growth and the still unstabilised hormonal regulation functions cannot be ruled out.
- During treatment your liver function, the function of a hormone producing gland (adrenocortical function) attached to the kidneys and the red blood-cell count should be checked regularly.
- In individual cases, disturbances of liver function, some of them severe (hepatitis and hepatic failure, which has been fatal in some cases), have been reported with high-dosed Androcur

treatment. Most reported cases are in males with carcinoma of the prostate. The disturbances of liver function are dose-related and develop, usually, several months after treatment has begun. Therefore, your doctor should monitor your liver function before treatment and during treatment especially if there are any symptoms or signs suggestive of liver toxicity (e.g. itching all over your body, yellowing of your skin).

- Benign and malignant liver changes have been reported in isolated cases. In very rare cases, liver tumours may lead to life-threatening internal bleeding. The doctor must therefore be informed of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time.
- If you suffer from diabetes, tell your doctor, since this disease requires strict supervision during treatment with Androcur Depot.
- Occasionally, Androcur Depot can lead to a sensation of shortness of breath.
- The occurrence of thromboembolic events has been reported in patients using Androcur Depot, although a causal relationship has not been established. Patients with previous arterial or venous thrombotic/ thromboembolic events (e.g. deep venous thrombosis, pulmonary embolism, and myocardial infarction) or with a history of cerebrovascular accidents ("stroke") or with advanced malignancies are at increased risk of further thromboembolic events.
- If you have carcinoma of the prostate inform your doctor if you have suffered in the past from 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) or if you suffer from sickle-cell anaemia or from severe diabetes with vascular changes because in these conditions a careful risk:benefit evaluation must be carried out in each individual case before Androcur Depot is prescribed by your doctor.
- As Androcur Depot is an oily solution, it must be injected intramuscularly. Experience shows that the short-lasting reactions (urge to cough, coughing fits, and respiratory distress) which occur in rare cases during or immediately after the injection of Androcur Depot can be avoided by injecting the solution extremely slowly.

Driving and using machines

Androcur Depot can lead to tiredness and diminished vitality and can impair your ability to concentrate (e.g. important for road users, machine operators, other occupations demanding great concentration).

Taking other medicines with Androcur Depot:

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

The requirement for oral antidiabetics or insulin can change.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. This particularly applies to medicines containing ketoconazole, itraconazole, clotrimazole, ritonavir, rifampicin, phenytoin, products containing St. John's wort, and to products belonging to the group of statins (medicines for lowering increased blood fats, e.g., cholesterol, triglycerides).

The risk of statin-associated muscle-tissue-related side effects (so-called myopathy or rhabdomyolysis) may be increased when certain statins are co-administered with high therapeutic cyproterone acetate doses since they share the same metabolic pathway.

PREGNANCY AND BREAST-FEEDING

Not applicable

HOW TO USE ANDROCUR DEPOT

Do not share medicines prescribed for you with others.

The injections must be administered very slowly. Androcur Depot is strictly for intramuscular injection. Special care must be given to avoid intravascular injection.

Reduction of drive in sexual deviations in males

In general, 1 ampoule of Androcur Depot is given as a deep intramuscular injection every 10 to 21 days. If, in exceptional cases, the effect is inadequate, 2 ampoules can be given every 10 to 21 days, preferably as 1 ampoule each in the right and left gluteal muscles. Efficacy can be maintained by injection intervals ranging from 10 to 21 days.

When the therapeutic result is considered to be satisfactory, an attempt should be made to reduce the dosage by gradually increasing the intervals between injections.

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

Inoperable carcinoma of the prostateAfter orchidectomy:

300 mg (1 ampoule) every 2 weeks as a deep IM injection.

Without orchidectomy:

300 mg (1 ampoule) weekly as a deep IM injection.

Treatment should not be interrupted nor the dosage reduced after improvement or remissions have occurred.

If more Androcur Depot has been used than should have been

Treatment is supportive and symptomatic.

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 get your Androcur Depot injection

Have a new appointment with your doctor in order to make up for the forgotten injection. You should not get a double dose.

POSSIBLE SIDE-EFFECTS

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

Androcur Depot can have side effects.

The most serious undesirable effects associated with the use of Androcur Depot are listed in section 'Take special care with Androcur Depot'.

It is very common to notice decreased libido (sexual desire), erectile dysfunction and reversible inhibition of sperm formation.

Common side effects are: increased or decreased weight, depressed mood, temporary restlessness, shortness of breath, liver toxicity (including jaundice, abnormal liver function tests and toxic hepatitis),

gynaecomastia (swelling of the breast glands), feeling of tension in the breasts, fatigue, hot flushes and sweating.

The less common side effects are: possible rash.

Rarely, you may experience conditions relating to thrombosis (the formation of a blood clot) in the blood vessels (thromboembolic process) or hypersensitivity.

Under treatment with Androcur Depot, sexual drive and potency are reduced and the function of the testicles is inhibited. These changes are reversible after discontinuation of therapy.

Over the course of several weeks, Androcur Depot inhibits the formation of sperms (spermatogenesis) as a result of the antiandrogenic and antigonadotropic actions. Spermatogenesis recovers gradually within a few months of discontinuing the therapy.

Androcur Depot may lead to swelling of the breast gland (so called gynaecomastia, sometimes combined with tenderness to touch of the mamillae) which usually regresses after withdrawal of the preparation. Permanent enlargement of the mammary glands may occur.

Long-term androgen deprivation with Androcur Depot may lead to osteoporosis.

IDENTIFICATION OF ANDROCUR DEPOT

Clear, colourless to faintly yellowish oily solution in 3 ml amber glass ampoules.

PRESENTATION OF ANDROCUR DEPOT

Amber glass ampoules of 3 ml.

STORING AND DISPOSING OF ANDROCUR DEPOT

Store below 30 °C. Protect from light.

Do not use Androcur Depot after the expiry date which is stated on the ampoule and the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

FINAL PIL

-7-

REGISTRATION NUMBER

R/21.12/184

NAME AND BUSSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

Reg. No.: 1968/011192/07

27 Wrench Road

ISANDO

1609

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

13 June 2009