

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
DOSAGE FORM: Solution for injection
STRENGTHS: 300,0 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ANDROCUR DEPOT 300 mg Solution for injection (for use in men) cyproterone acetate

Please read this leaflet carefully before you are given 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

What is in this leaflet

1. What ANDROCUR DEPOT is and what it is used for
2. What you need to know before you use ANDROCUR DEPOT
3. How to use ANDROCUR DEPOT
4. Possible side effects
5. How to store ANDROCUR DEPOT
6. Contents of the pack and other information

1. What ANDROCUR DEPOT is and what it is used for

ANDROCUR DEPOT is a hormone preparation acting against male sex hormones. (androgens). The active substance is cyproterone acetate. ANDROCUR reduces the testosterone (an androgen) concentration in the blood. This in turn leads to a reduction of sex drive.

Androgens encourage the growth of prostate cancer. In these patients, ANDROCUR inhibits this effect.

2. What you need to know before you use ANDROCUR DEPOT

ANDROCUR DEPOT should not be administered to you:

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 ANDROCUR DEPOT injection is given to you.

- 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”)

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
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STRENGTHS: 300,0 mg

- if you have or ever 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 or ever had a benign brain tumour (meningioma)
- if you suffer from 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.

Warning and precautions

Tell your doctor or health care provider before being given the injection if you have or have had any of the following conditions:

- If you suffer from diabetes, since he/she may need to adjust your antidiabetic medication. This requires strict supervision during treatment with ANDROCUR DEPOT (see also section ‘Do not take ANDROCUR’).
- Anaemia has been reported during treatment with ANDROCUR. Therefore, your doctor will monitor your red blood cell count during treatment.
- Blood clots
- Liver problems
- Depression
- Breathing problems (shortness of breath)

ANDROCUR may decrease the function of the hormone producing gland attached to the kidneys (adrenal glands). Therefore, your doctor may conduct some tests to monitor this effect during treatment with ANDROCUR.

If you are diagnosed with meningioma, your doctor will stop your treatment with cyproterone acetate(see section ‘Do not use ANDROCUR’).

Blood clots (thromboembolic events) have been reported in patients using ANDROCUR, although a direct link with ANDROCUR has not been established. Patients with a history of blood clots or with advanced tumours have an increased risk of suffering blood clots.

Tell your doctor if you have ever had an arterial or venous blood clot, such as a deep vein thrombosis, a clot in the lung (pulmonary embolism), a heart attack (myocardial infarction) or a stroke (cerebrovascular accident).

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
DOSAGE FORM: Solution for injection
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If you are being treated for prostate cancer, tell your doctor if you have ever suffered from any of the following as he/she will need to conduct a careful evaluation before deciding to prescribe ANDROCUR:

- a blood circulation disorder (especially blood clots)
- sickle cell anaemia
- severe diabetes with vascular changes

As with all oily solutions, your doctor will inject ANDROCUR strictly into a muscle and very slowly. The oily solution ANDROCUR DEPOT may reach the lungs (pulmonary microembolism of oily solutions) which can lead to signs and symptoms such as cough, shortness of breath (dyspnoea), chest pain. There may be other signs and symptoms known as vasovagal reactions such as malaise, increased sweating (hyperhydrosis), dizziness, ‘pins and needles’ (paraesthesia), or fainting (syncope). These reactions may occur during or immediately after the injection and are reversible. Treatment by your doctor is usually supportive. You may for example be given oxygen.

If you are being treated for the reduction of sex drive in cases of sexual deviations, the effect of ANDROCUR. may be reduced under the influence of alcohol.

Children and adolescents

ANDROCUR is not recommended for use in male children and adolescents below 18 years of age because safety and efficacy have not been established in this age group.

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

Other medicines and 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.

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

Tell your doctor in particular if you are taking statins (medicines for reducing blood fats), as high doses of ANDROCUR may worsen certain side effects (myopathy or rhabdomyolysis) which may occur during treatment with statins.

Also inform your doctor if you are taking other medicines which affect the liver, e.g.
- ketoconazole, itraconazole, clotrimazole (for fungal infections)

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
DOSAGE FORM: Solution for injection
STRENGTHS: 300,0 mg

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

High doses of ANDROCUR (100 mg 3 times per day) may block certain liver enzymes, which may influence the effect of other medicines.

ANDROCUR DEPOT with food and drinks

Not Applicable

Pregnancy and breastfeeding

Treatment with ANDROCUR (for use in men) is not indicated in women

Driving and using machines

ANDROCUR DEPOT can lead to tiredness and decreased energy and impair your concentration.

ANDROCUR DEPOT contains

Active ingredient is cyproterone Acetate

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

How to use ANDROCUR DEPOT

Do not share medicines prescribed for you with others.

Your doctor will inject ANDROCUR very slowly into a muscle avoiding all blood vessels.

Reduction of drive in sexual deviations in males

Your doctor will give you 1 ampoule of ANDROCUR DEPOT as a deep injection into a muscle every 10 to 21 days. Your doctor may increase the dose to 2 ampoules every 10 to 21 days, he/she will give you 1 ampoule each in the right and left buttock. Efficacy can be maintained by injection intervals ranging from 10 to 21 days.

When a satisfactory result has been achieved, your doctor will reduce the dosage by gradually increasing the intervals between your injections.

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
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STRENGTHS: 300,0 mg

To stabilise the therapeutic effect, it is necessary to use ANDROCUR DEPOT over a long period of time, your doctor may refer you for psychotherapy during this time.

Inoperable carcinoma of the prostate

After 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.

Do not change or interrupt the treatment or dosage prescribed by your doctor once you feel an improvement.

Elderly patients (65 years or older)

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

Patients with impaired liver function

Do not use ANDROCUR if you suffer from impaired liver function (see section 'Do not use ANDROCUR')

Patients with impaired kidney function

There are no data suggesting the need for a dosage adjustment in patients with impaired kidney function.

If you take more ANDROCUR DEPOT than you should

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.

Since a health care provider will administer ANDROCUR DEPOT, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to get your ANDROCUR DEPOT injection

Since a health care provider will administer ANDROCUR DEPOT, it is unlikely that the dose will be missed.

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
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If you stop using ANDROCUR DEPOT

Do not stop using ANDROCUR unless your doctor has told you to do so. If you want to stop using ANDROCUR, you should discuss this with your doctor first.

4. Possible side effects

ANDROCUR DEPOT can have 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.

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

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 movements, dark coloured urine. These symptoms could be signs of liver toxicity, including inflammation of the liver (hepatitis) or liver failure.

Disturbances of liver function, some of them severe (jaundice hepatitis and hepatic failure), have been observed in patients with ANDROCUR. At dosages of 100 mg and above also fatal cases have been reported. Most reported fatal cases were in men with advanced prostate cancer. 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 your treatment with ANDROCUR, unless the liver toxicity can be explained by another cause (e.g. secondary tumours). In this case your doctor may continue your treatment with ANDROCUR if the perceived benefit outweighs the risk.

- Unusual upper abdominal pains which do not disappear spontaneously within a short time. These symptoms could be signs of benign or malignant liver tumours which may lead to life-threatening internal bleeding (intra-abdominal haemorrhage).

- Swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak. These symptoms could be signs of formation of blood clots (thromboembolic events).

Very common side effects: may affect more than one in 10 people.

- reversible inhibition of sperm production (spermatogenesis)

APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: ANDROCUR DEPOT
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- reduced sexual drive (libido decreased)
- inability to achieve or maintain an erection (erectile dysfunction)

Common side effects: may affect more than one in 10 people.

- liver toxicity, including jaundice, inflammation of the liver (hepatitis), liver failure
- weight gain
- weight loss
- depressed mood
- temporary restlessness
- enlarged breasts (gynaecomastia)
- tiredness (fatigue)
- hot flushes
- sweating
- shortness of breath

Uncommon side effects: may affect more than one in 10 people

- rash

Rare side effects: may affect more than one in 10 people

- allergic reaction (hypersensitivity)

Very rare side effects: may affect more than one in 10 people

- benign and malignant liver tumours

Side effects for which frequency is not known:

- internal bleeding (intra-abdominal haemorrhage)
- formation of blood clots (thromboembolic events) (see section 'Take special care with ANDROCUR')
- pulmonary oil microembolism with symptoms such as cough, shortness of breath (dyspnoea), or chest pain (see section 'Take special care with ANDROCUR')
- vasovagal reactions with symptoms such as malaise, increased sweating (hyperhidrosis), dizziness, 'pins and needles' (paraesthesia), or fainting (syncope) (see section 'Take special care with ANDROCUR')
- benign brain tumours (meningiomas) (see sections 'Do not use ANDROCUR' and 'Take special care with ANDROCUR')
- osteoporosis
- anaemia

APPLICANT: BAYER (PTY) LTD
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Under treatment with ANDROCUR DEPOT, sexual drive and potency are reduced and the function of the testicles is inhibited. These changes are reversible after ANDROCUR DEPOT treatment has been discontinued.

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 ANDROCUR treatment has been discontinued. Permanent enlargement of the mammary glands may occur.

Long-term use of ANDROCUR DEPOT may lead to osteoporosis.

Benign brain tumours (meningiomas) have been reported in association with long-term use (several years) of ANDROCUR doses of 25 mg and above. (see sections 'Do not use ANDROCUR' and 'Take special care with ANDROCUR').

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ANDROCUR DEPOT.

5. How to store 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.

APPLICANT: BAYER (PTY) LTD
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6. Contents of the pack and other information

What ANDROCUR DEPOT contains

The active ingredient is cyproterone acetate

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

What ANDROCUR DEPOT looks like and contents of the pack

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

Holder of Certificate of Registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
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