

ANDROCUR 50

Please read this leaflet carefully before you start your treatment.

A guide to using Androcur 50 Tablets

This leaflet gives you some information about Androcur 50. Additional information is available from your doctor or pharmacist.

Androcur contains cyproterone acetate. This substance is an antiandrogen. That is, it blocks the actions of male sex hormones (androgens). It also reduces the amount of male sex hormones produced by the body.

The reason why you can only obtain this medicine on prescription is that it may only be used under careful medical supervision.

Please tell your doctor if you have any doubts or worries about using this medicine, either before you start or while you are using it.

The name of your medicine is:

Androcur 50 (cyproterone acetate)

What does your medicine contain?

Each pack contains 50 tablets, each containing 50mg cyproterone acetate.

Each tablet also contains the inactive ingredients:

maize starch
povidone
colloidal anhydrous silica
magnesium stearate (E 572)
lactose

Androcur is an antiandrogen therapy. That is, it blocks the actions of male sex hormones (androgens).

The product licence is held by

HE Clissmann
44 Dartmouth Square
Dublin 6

Product Authorisation number:

PA 12/5/1

Androcur is manufactured by:

Schering AG
Mullerstrasse 178
13342 Berlin
and

Schering GmbH und Co Produktions KG
Döbereinerstraße 20
99427 Weimar
Germany

Uses

Androcur 50 is used to control libido in adult males who have increased sex drive (hypersexuality) and/or sexual deviation.

Androcur 50 is also used to treat cancer of the prostate gland which may be dependent on male hormones.

Reasons for not taking Androcur

You should not take Androcur if you have any of the following:

- liver diseases (including previous or existing liver tumours)
- any type of cancer (other than cancer of the prostate gland)
- wasting diseases
- blood clots (thrombosis or embolism) or have ever had these
- severe diabetes that affects your circulation of blood
- abnormal red blood cells (sickle-cell anaemia)
- severe depression which you have had for many months
- allergy to any of the components of Androcur 50

However, in patients with cancer of the prostate gland, your doctor may decide that Androcur 50 should be used even though you suffer from some of these conditions.

You should not use Androcur if you are under 18 years of age or if you are not yet a fully grown adult in every way.

Androcur 50 should not be used in females.

What you should know before taking Androcur 50 tablets

You will notice a reduction in your sexual desire while you are taking this medicine.

When you have been taking Androcur 50 for some months, you will probably become unable to make anyone pregnant, but note that this does **not** happen at once, and you should not rely on Androcur 50 for contraception at any time. While the overall number of sperms that you produce will be reduced, more of your sperms than usual will be abnormal in shape. Some people think these abnormal sperms might possibly produce abnormal babies. Your doctor will be able to advise you further if you are thinking of having children.

Androcur 50 does not work well in men who regularly drink a lot of alcohol.

Cyproterone acetate can increase the sugar in your blood, and if you are diabetic your doctor will check this regularly.

Disturbances of liver function, some of them severe, have been reported with high-dosed cyproterone acetate

treatment. Your doctor may arrange for you to have regular liver tests during treatment.

As with other sex steroids, benign and malignant liver changes have been reported in isolated cases. In very rare cases, liver tumours may lead to life-threatening bleeding in the abdomen. Tell your doctor if you have any new "stomach" discomfort or pain that does not soon clear up.

Effects on the blood (anaemia) and adrenal glands have also been reported rarely during long-term treatment with cyproterone acetate. Your doctor may arrange for you to have regular blood tests during treatment.

Tiredness and weakness can occur, especially during the first few weeks of treatment. You should not drive or operate machinery under these conditions.

As with other antiandrogenic treatments, long-term androgen deprivation with Androcur 50 may lead to osteoporosis in very rare cases.

What you should know if you take other drugs

If you are diabetic your doctor may alter the dose of medicine required to treat your diabetes.

How to take Androcur 50

Read the instructions on the label carefully and take the tablets as instructed. The tablets should be taken after meals and swallowed whole with a drink of water.

In the treatment of increased sex drive or sexual deviation, the usual starting dose is one tablet twice daily. This may be increased or decreased depending on the response to treatment.

In the treatment of cancer of the prostate, the usual dose is one or two tablets once or twice daily but higher doses may be used.

Overdosage

There have been no reports of serious ill-effects from overdosage. You should consult your doctor who will be able to advise you what action, if any, is necessary.

What to do if you miss a dose

If you have forgotten to take your medicine, do not make up for it by taking extra tablets. When you remember, take the next prescribed dose and continue with the treatment. If you are concerned, consult your doctor or pharmacist.

Side-effects

Discomfort or even enlargement of the breasts occurs in some patients and, in rare cases, there may be tender lumps in the breasts and oozing of milky fluid from the nipples. These effects usually disappear if treatment is stopped or if the dose of Androcur is reduced.

Some patients taking this medicine have noticed breathlessness.

If you have to take cyproterone acetate for a long time, you may notice a change in your weight, usually an increase.

You may feel tired, weak or listless, especially during the first few weeks of treatment. In extremely rare cases, blood clots (thrombosis or embolism) have been reported in patients taking this medicine. However, these have not been definitely linked to cyproterone acetate.

You should ask your doctor about any change in health or general sense of well-being that you notice while taking Androcur 50.

Expiry date: The expiry date is printed on the pack. Do not use after this date.

Storage: Keep your medicine out of the reach and sight of children. Store below 30°C.

Date of last revision of this leaflet:
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