

CYPROTERONE SANDOZ®

cyproterone acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cyproterone Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Cyproterone Sandoz is used for

MEN:

This medicine is used to treat cancer of the prostate gland. It can also be used in conjunction with other medicines or following surgical removal of the testes to treat side effects such as "hot flushes" or "sweats" and to prevent any initial worsening of the disease.

It is also used for the reduction of sex drive in men with sexual deviations.

WOMEN:

This medicine is used to treat:

- excessive hairiness (hirsutism)
- androgen-dependent loss of scalp hair (androgenic alopecia)
- dandruff
- acne
- oily skin.

It contains the active ingredient cyproterone acetate.

Cyproterone acetate belongs to a group of medicines called anti-androgen hormones.

It works by blocking androgens (e.g. testosterone), which are natural male sex hormones. Androgens are also produced, to a slight extent, in females.

In men, androgens may help cancer cells to grow in some types of prostate cancer. By blocking these hormones, Cyproterone Sandoz may slow or stop the growth of cancer.

In women, androgens may increase hair growth, loss of scalp hair and secretion of oil from the sweat glands. By blocking these hormones, Cyproterone Sandoz may slow or stop excessive hairiness, loss of scalp hair, acne, oily skin and dandruff.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Cyproterone Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- cyproterone acetate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have any of the following medical conditions:

- liver disease or liver tumours unless they are caused by metastases from prostate cancer
- severe chronic depression
- Dubin-Johnson or Rotor syndrome
- wasting disease (a disease causing muscle loss or loss of strength, with the exception of prostate cancer)
- severe diabetes that has damaged your blood vessels
- sickle-cell anaemia
- existing blood clots
- benign brain tumour (meningioma).

Do not take this medicine if you have had any of the following medical conditions:

- liver tumours
- jaundice (yellowing of the skin and/or eyes), herpes or persistent itching during a previous pregnancy
- history of blood clotting problems (e.g. blood clots in the leg, lungs, stroke or heart attack)
- benign brain tumour (meningioma).

In men with cancer of the prostate with some of the above medical conditions, the benefits of taking this medicine may outweigh the risks. Your doctor will consider the risks and benefits of taking this medicine.

Do not take this medicine if you are pregnant or suspect you may be pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Cyproterone Sandoz passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children.

This medicine should not be taken by children and adolescents below 18 years of age or girls who have not completed puberty.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes
- history of blood clotting or sickle cell anaemia
- osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines)
- amenorrhea (no menstrual periods)
- a hysterectomy (surgical removal of the uterus).

Tell your doctor if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. Therefore, your doctor will check that you are not pregnant before you start taking Cyproterone Sandoz.

Women should use a reliable form of contraception while taking Cyproterone Sandoz.

Tell your doctor if fertility after treatment is important.

It is advisable for men to have a spermatogram before taking Cyproterone Sandoz to establish your fertility. It can take 3-20 months for fertile sperm production to be re-established after stopping this medicine.

The long-term effects of Cyproterone Sandoz on female fertility are not known.

Cyproterone Sandoz contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

If you have not told your doctor about any of the above, tell him/her before you start taking Cyproterone Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Cyproterone Sandoz may interfere with each other. These include:

- medicines used to treat fungal infections, such as ketoconazole, itraconazole, clotrimazole
- rifampicin, an antibiotic used to treat infections such as tuberculosis and leprosy
- ritonavir, a medicine used in the treatment of HIV
- St John's Wort, a herbal remedy used to treat mood disorders
- phenytoin, a medicine used to treat epilepsy
- statins (HMGCoA inhibitors), medicines used to lower cholesterol levels
- medicines used to treat diabetes, such as oral anti-diabetic medicines or insulin.

These medicines may be affected by Cyproterone Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Cyproterone Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

MEN:

Your doctor will tell you the dose that you should take.

Do not alter the dose yourself.

Prostate cancer:

The usual daily dose is 50-300 mg (half to three tablets) of Cyproterone Sandoz 100 mg.

Your doctor may request that you take Cyproterone Sandoz with other medicines and/or change your dose during treatment.

Reduction of drive in sexual deviations:

The usual starting dose is one tablet of Cyproterone Sandoz 50 mg twice daily.

Your doctor may change your dose during treatment.

WOMEN:

Your doctor will tell you the dose that you should take and when to start taking Cyproterone Sandoz.

When you start taking Cyproterone Sandoz depends on whether you:

- are of childbearing age
- have amenorrhea (no menstrual periods)
- have had a hysterectomy (surgical removal of the uterus)
- are post menopausal.

Additionally, your doctor will advise the most appropriate "Pill" for you to take to provide the necessary contraceptive protection and to stabilise your menstrual cycle.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Cyproterone Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water after meals.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

Missed Cyproterone Sandoz tablets in women may reduce the effectiveness of treatment and may lead to intermenstrual bleeding.

If you are also taking the "Pill" and more than 12 hours has elapsed from the time Cyproterone Sandoz was due to be taken, note that contraceptive protection may be reduced and thus there is an increased risk of becoming pregnant.

If bleeding fails to occur after a cycle where the "Pill" was missed, you must see your doctor.

Your doctor may need to check whether or not you are pregnant before you can continue treatment.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Cyproterone Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Cyproterone Sandoz

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Cyproterone Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

For females taking the "Pill" during treatment:

If light bleeding or spotting occurs during the three weeks in which the tablets are being taken, do not stop taking your tablets.

However, if unusual bleeding patterns continue, tell your doctor.

If no bleeding occurs during the tablet-free/placebo interval, tell your doctor.

Your doctor may need to check whether you are pregnant before you can continue treatment.

For males taking Cyproterone Sandoz to reduce abnormal sex drive:

You should consider undertaking additional measures such as therapy or counselling in order to take advantage of the period of reduced drive. These measures may assist in achieving personal and social reorientation.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as liver or blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Your doctor will check your liver function during treatment Cyproterone Sandoz and

whenever any symptoms or signs suggesting liver problems are observed.

If you have diabetes, your doctor will monitor you to ensure that you receive the appropriate dose of oral antidiabetic or insulin whilst taking Cyproterone Sandoz.

Your doctor will also check your red-blood cell count to ensure you do not become anaemic during treatment with Cyproterone Sandoz.

Things you must not do

Do not take Cyproterone Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Cyproterone Sandoz affects you.

This medicine may cause tiredness and can impair the ability to concentrate in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, tiredness and the ability to concentrate may be worse.

If you are taking Cyproterone Sandoz to reduce your sex drive, alcohol may stop Cyproterone Sandoz from working as well as it should.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cyproterone Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- tiredness, fatigue
- weight changes (increase or decrease)
- decreased sexual drive
- headache
- depressed mood
- nausea and other stomach complaints
- breast pain, changes in breast size, breast swelling and/or tenderness
- breast enlargement in men
- irregular menstrual cycle, spotting
- hot flushes, sweating
- shortness of breath
- osteoporosis.

The above list includes the more common side effects of the medicine.

If you were fertile before treatment, Cyproterone Sandoz may also result in the inability to produce sperm (males) or ovulate (females). In males, fertility is usually regained within a few months of discontinuing therapy. The long-term effects on female fertility are not known.

In males, Cyproterone Sandoz may result in the inability to get or maintain an erection (impotence). This is usually regained within a few months of discontinuing therapy.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the skin and/or eyes, light coloured bowel motions, dark coloured urine (jaundice)
- severe upper abdominal pain
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- signs of a stroke, such as sudden severe headache, loss of vision, loss of co-ordination, slurred speech, numbness, heat or swelling in the arms and legs
- signs of a heart attack, such as chest pain or shortness of breath.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Cyproterone Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Cyproterone Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Cyproterone Sandoz comes in two types of tablets:

Cyproterone Sandoz 50 mg – white to off white, round tablets engraved with ‘50’ over a break line on one face, plain on the other face.

Available in bottles of 20 or 50 tablets.

Cyproterone Sandoz 100 mg – white to off white, capsule shaped tablets with ‘100’ engraved on one face and a break line on the other face.

Available in blisters of 50 tablets.

Ingredients

Active ingredients:

- Cyproterone Sandoz 50 mg - 50 mg cyproterone acetate
- Cyproterone Sandoz 100 mg - 100 mg cyproterone acetate

Inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- povidone
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Cyproterone Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

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Australian Register Number(s)

50 mg tablets: AUST R 107330 (*bottles*)

100 mg tablets: AUST R 107331 (*blisters*)