

Cyproterone Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Cyproterone Sandoz?

Cyproterone Sandoz contains the active ingredient cyproterone acetate. In men, Cyproterone Sandoz is used for reduction of sex drive in cases of sexual deviations in men, as well as for antiandrogen treatment in inoperable prostate cancer. In women, Cyproterone Sandoz is used to slow or stop moderately severe to severe signs of androgenisation such as excessive hairiness, loss of scalp hair, acne, oily skin and dandruff.

For more information, see Section [1. Why am I using Cyproterone Sandoz?](#) in the full CMI.

2. What should I know before I take Cyproterone Sandoz?

Do not use if you have ever had an allergic reaction to cyproterone acetate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Cyproterone Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cyproterone Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Cyproterone Sandoz?

In men, for prostate cancer, the usual daily dose is 50-300 mg of Cyproterone Sandoz. In women, the dose is 50-100 mg of Cyproterone Sandoz daily from the 1st to the 10th day of the cycle. Your doctor will advise of the most suitable dose for you to take. Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I take Cyproterone Sandoz?](#) in the full CMI.

5. What should I know while taking Cyproterone Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Cyproterone Sandoz.• Your doctor may do liver function tests and red-blood cell count to make sure the medicine is working and to prevent unwanted side effects.• Tell your doctor if you have diabetes
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.• Do not take Cyproterone Sandoz to treat any other complaints unless your doctor tells you to
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, tiredness and the ability to concentrate may be worse.• Alcohol may prevent Cyproterone Sandoz from working as well as it should in reducing abnormal sex drive.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 30 °C.• Keep your tablets in the pack until it is time to take them

For more information, see Section [5. What should I know while taking Cyproterone Sandoz?](#) in the full CMI.

6. Are there any side effects?

The serious side effects include yellowing of the skin and/or eyes, light coloured bowel motions, dark coloured urine, 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, sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in the arms and legs, hearing loss, memory loss, seizures and weakness in the arms or legs.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cyproterone Sandoz®

Active ingredient(s): *cyproterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cyproterone Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cyproterone Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Cyproterone Sandoz?](#)
- [2. What should I know before I take Cyproterone Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Cyproterone Sandoz?](#)
- [5. What should I know while taking Cyproterone Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cyproterone Sandoz?

Cyproterone Sandoz contains the active ingredient cyproterone acetate. Cyproterone Sandoz is an antiandrogen medicine. It works by blocking the effect of androgens, which are natural sex hormones produced mainly in males but 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.** Cyproterone Sandoz may also be used in combination 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.

Cyproterone Sandoz is also used to reduce abnormal sex drive in men.

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.**

2. What should I know before I take Cyproterone Sandoz?

Warnings

Do not use Cyproterone Sandoz if:

- you are allergic to cyproterone acetate, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- Do not use Cyproterone Sandoz if you have any of the following medical conditions:
 - liver disease, previous or existing liver tumours unless they are caused by metastases from prostate cancer (your doctor would have told you if you have this)
 - Dubin-Johnson or Rotor syndrome (your doctor would have told you if you have either of these conditions)
 - history of jaundice (yellow skin or eyes), herpes or persistent itching during a previous pregnancy
 - previous or existing benign brain tumour (meningioma)
 - wasting disease (a disease-causing muscle loss or loss of strength, with the exception of prostate cancer)
 - severe and persistent depression
 - previous or existing conditions relating to formation of blood clots
 - severe diabetes with blood vessel changes (your doctor would have told you if you have this)
 - sickle-cell anaemia (your doctor would have told you if you have this)

Check with your doctor if you:

- have any other medical conditions, especially following:
 - 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)
- take any medicines for any other condition
- have an intolerance to some sugars, Cyproterone Sandoz tablets contains lactose monohydrate
- have any allergies to any other medicines, foods, preservative or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If taken during pregnancy, Cyproterone Sandoz may lead to signs of feminisation in the male foetus. 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.

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.

Tell your doctor if fertility after treatment is important

- For men it is recommended that a sperm count is taken to establish fertility before commencing Cyproterone Sandoz. 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 should not be taken by children and adolescents below 18 years of age or girls who have not completed puberty.

3. What if I am taking other medicines?

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

Some medicines may interfere with Cyproterone Sandoz and affect how it works.

- phenytoin, a medicine used to treat epilepsy
- medicines used to treat fungal infections, including ketoconazole, itraconazole, clotrimazole
- ritonavir, a medicine used in the treatment of HIV
- rifampicin, an antibiotic used to treat infections such as tuberculosis and leprosy
- St John's wort, a herbal remedy used to treat mood disorders
- statins (HMGCoA inhibitors), medicines used to lower cholesterol levels in people with or at risk of cardiovascular disease
- medicines used to treat diabetes

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cyproterone Sandoz.

4. How do I take Cyproterone Sandoz?

How much to take

Follow the instructions provided and take Cyproterone Sandoz until your doctor tells you to stop.

MEN:

- For **Prostate cancer**, the dose is 50-300 mg of Cyproterone Sandoz. Your doctor may request you

take Cyproterone Sandoz with other medicines and/or change your dose during treatment.

- For **Reduction of abnormal sex drive**, generally treatment is started with 50 mg of Cyproterone Sandoz twice daily and may be increased to 100 mg twice daily or three times daily before reducing gradually to the lowest effective dose. Your doctor may change your dose during treatment.

WOMEN:

- If you are of childbearing age, you should commence your tablet taking on the 1st day of your cycle (= 1st day of bleeding). If you have no menstrual periods (amenorrhoea) your treatment can start immediately. In this case, the first day of treatment is to be regarded as the 1st day of the cycle.
- Starting from day 1 take 50-100 mg (as advised by your doctor) of Cyproterone Sandoz daily from the 1st to the 10th day of the cycle (= for 10 days). Additionally, your doctor will advise the most appropriate contraceptive for you to take to provide the necessary contraceptive protection and to stabilise your cycle.
- Your doctor will re-evaluate your treatment when you reach menopause. Long-term use (years) of Cyproterone Sandoz should be avoided.
- If you are postmenopausal or have had a hysterectomy, Cyproterone Sandoz may be administered alone. The usual dose is 25-50 mg of Cyproterone Sandoz once daily for 21 days, followed by a 7-day tablet-free interval. Shortness of breath may occur at high doses.

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

When to take Cyproterone Sandoz

- Cyproterone Sandoz should be taken whole, with some liquid after meals.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

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

If you forget to use Cyproterone Sandoz

- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.
- Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.
- If you are also taking an oral contraceptive and more than 12 hours has elapsed from the time Cyproterone Sandoz was due to be taken, note that contraceptive protection in this cycle may be reduced and thus there is an increased risk of becoming pregnant.

If you use too much Cyproterone Sandoz

If you think that you have used too much Cyproterone Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Cyproterone Sandoz?

Things you should do

- Your doctor may do some 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 with 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.
- If you are a female taking an oral contraceptive during treatment, tell your doctor if your period does not occur during the tablet-free / placebo interval. Your doctor may need to check whether you are pregnant before you can continue treatment.
- If you are a male 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 re-orientation.

Remind any doctor, dentist or pharmacist you visit that you are using Cyproterone Sandoz.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cyproterone Sandoz affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Alcohol may prevent Cyproterone Sandoz from working as well as it should in reducing abnormal sex drive.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• tiredness, fatigue• weight change• headache• depressive mood• nausea and other gastrointestinal complaints• decreased sexual drive• breast pain, change in breast size, breast swelling and/or tenderness• breast enlargement in men• menstrual cycle irregularity, spotting• hot flushes, sweating• shortness of breath• osteoporosis	Speak to your doctor if you have any of these less serious side effects and they worry you.

If you were fertile before treatment, Cyproterone Sandoz will normally prevent sperm production in men and ovulation in women. In men, fertility is usually regained within a few months of discontinuing therapy. The long term effects on female fertility are not known.

In men Cyproterone Sandoz will also normally result in the inability to get or maintain an erection (impotence). This

ability is usually also regained within a few months of discontinuing therapy.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">yellowing of the skin and/or eyes, light coloured bowel motions, dark coloured urinesevere upper abdominal painvomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoeasudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in the arms and legs	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Use of cyproterone acetate has been linked to the development of meningioma (generally benign tumour). The risk increases when used for several years, or with high doses (25 mg per day and above).

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smellheadaches that worsen with time, memory loss, seizuresweakness in your arms or legs	Call your doctor straight away, if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Cyproterone Sandoz contains

Active ingredient (main ingredient)	cyproterone acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratemicrocrystalline cellulosecroscarmellose sodiumpovidonemagnesium stearate
Potential allergens	lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Cyproterone Sandoz looks like

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. (Aust R 107330).

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. (Aust R 107331).

Not all pack sizes may be available in Australia.

Who distributes Cyproterone Sandoz

Sandoz Pty Ltd
100 Pacific Highway
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