

APO-Cyproterone 50 mg Tablets

Contains the active ingredient cyproterone (as cyproterone acetate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about cyproterone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Cyproterone 50 mg. It is an anti-androgen medicine. It contains the active ingredient cyproterone (as cyproterone acetate).

It is used to treat:

- women who have a problem with facial or chest hair, are balding, have severe acne and/or secrete excess oil from the sweat glands.
- men with cancer of the prostate. It can also be used in conjunction with other medications 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.
- men with sexual deviations.

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

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

How it works

This medicine works by reducing the effects and the level of male sex hormones in the body (which are also produced in females to a lesser extent).

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

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

- **You are pregnant or suspect you may be pregnant**
Cyproterone may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding**
Cyproterone may pass into human breast milk and there is a possibility that your baby may be affected.
- **You have or have had liver disease or liver tumours**
Except if they are caused by metastases from prostate cancer (your doctor would have told you if you have this).
- **You have previously had herpes or jaundice or persistent itching whilst pregnant**
- **You have Dubin-Johnson or Rotor syndrome.**
(Your doctor would have told you if you have this).
- **You have or have had meningioma, a type of brain tumour.**
- **You have a wasting disease or sickle cell disease**

- **You have severe and persistent depression**
- **You have or have had problems with your blood clotting or blood clots**
- **You have severe diabetes which involves serious changes in blood flow through the veins**
- **You have not yet completed puberty**
- **You are hypersensitive to, or have had an allergic reaction to, cyproterone or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - problems with blood clotting or blood clots
 - heart attack or stroke
 - problems with your eyesight
 - diabetes

- a close family history of breast cancer, or any physical changes (e.g. breast nodules)
 - 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)
 - anaemia or sickle cell anaemia
 - the Lapp-Lactase deficiency or lactose intolerance. These tablets contain lactose.
3. You are planning to have surgery or an anaesthetic.
 4. You are currently receiving or are planning to receive dental treatment.
 5. You are pregnant, planning on becoming pregnant or are breastfeeding.
 6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with cyproterone. These include:

- statins, used for lowering cholesterol
- antibiotics such as rifampicin or penicillins
- medicine to control fits (phenytoin)
- medicines to treat diabetes
- medicine to treat fungal infections (ketoconazole, itraconazole, clotrimazole)
- medicine to treat HIV infections (ritonavir)
- St John's wort, a herbal remedy for depression.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with cyproterone.

Women must have a thorough medical and pelvic examination, including a Pap smear and breast examination, before taking cyproterone.

Your doctor will also make sure that your symptoms are not due to any other causes of androgenisation e.g. Cushing's syndrome, ovarian tumours, adrenal carcinoma and androgenital syndrome before starting treatment. You must not be pregnant or plan to become pregnant when taking cyproterone.

It is not known how cyproterone affects female fertility in the long term.

Men should be aware that cyproterone causes a decrease in sperm count. It may take 3 to 20 months for the sperm count to return to normal once therapy has been stopped. Men may need to have a sperm count.

Most reported cases of liver damage are in men with prostate cancer. Liver damage may be fatal in some cases. Such effects are more likely to happen when taking high doses of cyproterone and develop, usually, several months after treatment has begun. Your doctor will order liver function tests before you start taking cyproterone and whenever any symptoms or signs that suggest you have liver damage, for example jaundice (yellow skin and/or eyes), dark coloured urine. If you develop any of these signs you should contact your doctor immediately.

If you are required to concentrate (e.g. road users, machine operators) you should note that cyproterone acetate can make you feel tired or lethargic and can impair your ability to concentrate.

You may not be able to take this medicine if you drink alcohol. If you are taking this medicine to reduce your sex drive, alcohol may stop this medicine working as well as it should.

How to take this medicine

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

Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

MEN:

Prostate cancer

The usual daily dose is 50-300 mg of APO-Cyproterone Acetate 50 mg. Your doctor may request you take APO-Cyproterone Acetate 50 mg with other medicines and/or change your dose during treatment.

Reduction of abnormal sex drive

Generally treatment is started with 50 mg of APO-Cyproterone Acetate 50 mg 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 APO-Cyproterone Acetate 50 mg 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 APO-Cyproterone Acetate 50 mg should be avoided.

If you are postmenopausal or have had a hysterectomy, APO-Cyproterone Acetate 50 mg may be administered alone. The usual dose is 25-50 mg of APO-Cyproterone Acetate 50 mg once daily for 21 days, followed by a 7-day tablet-free interval.

Shortness of breath may occur at high doses.

How to take it

The tablets should be swallowed with some liquid (after food).

When to take it

Take this medicine at about the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

The tablets should be taken immediately after food.

How long to take it for

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

Make sure you have enough to last over weekends and holidays.

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

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you are also taking an oral contraceptive and more than 12 hours has elapsed from the time APO-Cyproterone 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 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant.
Tell your doctor immediately if you become pregnant.
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Your doctor will check your liver function during treatment 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.

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you develop any signs of liver toxicity - yellow skin or eyes - tell your doctor immediately. Your doctor will make sure this is not due to any other cause, e.g. metastatic disease (spread of cancer) and will decide if you should keep taking cyproterone.

In very rare cases liver tumours may lead to life-threatening intra-abdominal haemorrhage. If you develop severe upper abdominal complaints or tenderness tell your doctor immediately.

A sensation of shortness of breath may occur in some people who are taking high doses of cyproterone acetate. If this occurs, tell your doctor.

Female patients who are taking APO-Cyproterone Acetate 50 mg in combination with ethinyloestradiol, that have a family history of breast cancer should have regular breast examinations.

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 APO-Cyproterone Acetate 50 mg 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.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. This medicine may cause drowsiness and loss of concentration in some people.

Female patients should not smoke whilst taking APO-Cyproterone Acetate 50 mg in combination with ethinyloestradiol. Use of any oral contraceptives may be associated with an increased risk of heart attack and stroke.

Female patients should be aware that the contraceptive action of the combined treatment of APO-Cyproterone Acetate 50 mg and ethinyloestradiol may be reduced by diarrhoea or vomiting shortly after taking a tablet. In these cases, an additional form of contraception such as a condom or diaphragm should be used for the remainder of the cycle. In women taking APO-Cyproterone Acetate 50 mg in combination with ethinyloestradiol, if light bleeding or spotting occurs during the 3 weeks in which the tablets are being taken, do not stop taking your tablets.

However, if unusual bleeding continues or if bleeding is heavy, consult your doctor immediately.

If you are a male patient and you are taking this medicine to reduce your sex drive, be careful when drinking alcohol. Alcohol may stop APO-Cyproterone Acetate 50 mg from working as well as it should.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking cyproterone or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Infertility and impotence are expected effects of cyproterone acetate and cannot generally be avoided.

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

This list includes the more common side effects. Mostly, these are mild:

- tiredness, fatigue
- weight changes
- headache
- changes in sex drive
- nausea and gut upset
- unusual secretion of breast milk
- sleep disturbances
- hot flushes
- restlessness

If you were fertile before treatment, APO-Cyproterone Acetate 50 mg 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 APO-Cyproterone Acetate 50 mg 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.

In men, long-term use of cyproterone may uncommonly lead to osteoporosis.

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).

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- depressive moods
- blood clotting (which may lead to a clot on the lungs, stroke or heart attack)
- menstrual cycle changes, vaginal discharge, period pain in women
- gynaecomastia (swelling of the breast area which is sometimes also associated with tenderness or sensitivity). This usually goes away after reducing the dose or stopping the tablets
- fast heart rate
- change in skin colour (yellowing) or appearance of rashes
- shortness of breath.
- osteoporosis

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- severe pain and/or swelling in the stomach and gut
- pain in the groin, chest or leg
- swelling of one leg with tenderness or pain
- coughing up blood or sudden shortness of breath
- upper abdominal pain, yellowing of the eyes or skin (jaundice), itching, dark urine, feeling generally unwell and having poor appetite. These may be due to problems with your liver.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to cyproterone, do

not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Some additional side effects may occur in women taking APO-Cyproterone Acetate 50 mg in combination with ethinyloestradiol.

See your doctor immediately if you experience any of the following:

- Severe migraine headache for the first time, or a change in the pattern of your migraine
- Unusually bad headaches or headaches more often than before
- Change or loss of eyesight
- Rise in blood pressure.

In women, ovulation is inhibited under the combined treatment: APO-Cyproterone Acetate 50 mg in combination with ethinyloestradiol, so that it is not possible to become pregnant.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C. Protect it from light and moisture.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Cyproterone 50 mg looks like

White to off white, flat, round tablet with '50' engraved over a break line on one face, the other a plain face.

APO-Cyproterone 50 mg tablets are presented in bottles containing either 20 or 50 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 50 mg of cyproterone (as cyproterone acetate) as the active ingredient.

It also contains the following inactive ingredients:

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

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Cyproterone 50 mg tablets:
Bottles:
AUST R 101534.

Sponsor

Apotex Pty Ltd
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