

PROCUR

Cyproterone acetate

50 mg and 100 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking Procur

This leaflet answers some common questions about Procur. 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 Procur 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 Procur is used for

Procur tablets contain the active ingredient cyproterone acetate. Cyproterone acetate is an antiandrogen. It works by blocking the actions of sex hormones (androgens) that are produced mainly in men but also, to a lesser extent in women.

In men, Procur is used:

- to treat prostate cancer
- to control sexual desire in men who have an increased sex drive (hypersexuality) and/or sexual abnormalities.

In women, Procur is used:

- to treat severe signs of androgenisation such as excessive hair growth.

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

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

Before you take Procur

When you must not take it

Do not take Procur if you have an allergy to:

- any medicine containing cyproterone acetate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

Do not take Procur if:

- you are allergic to cyproterone acetate or any other ingredient listed at the end of this leaflet
- you are pregnant
- you are breastfeeding
- you suffer from liver diseases (including previous or existing liver tumours, Dubin-Johnson syndrome or Rotor syndrome)
- you have a history of jaundice (yellowing of skin and/or eyes) or persistent itching during a previous pregnancy
- you have a history of herpes in pregnancy
- you suffer from severe depression which you have had for many months
- you have previous or existing blood clots (thrombosis or embolism)
- you have abnormal red blood cells (sickle-cell anaemia)
- You have severe diabetes that affects your blood circulation

- you have previous or existing benign brain tumour (meningioma)
- you have wasting disease (a disease causing muscle loss or loss of strength, with the exception of prostate cancer)

Procur contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Procur.

If you are a male your doctor may instruct you to have a sperm count recorded before starting treatment. There may be a reduction in the overall number of sperm during the treatment but it will gradually recover after you have stopped the treatment. The long-term effects on female fertility are not known

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor if:

- 1. you suffer from** liver disease, previous or existing liver tumours, previous or existing benign brain tumours, diabetes, shortness of breath, history of blood clotting, sickle cell anaemia or anaemia.
- 2. you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 3. you are pregnant or intend to become pregnant.**
- 4. you are breastfeeding or planning to breastfeed.**

It is known that cyproterone acetate passes into breastmilk). Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Procur.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Procur.

Some medicines may interfere with Procur. These include:

- medicines used to treat diabetes
- medicines used to treat fungal infections, including ketoconazole, itraconazole, clotrimazole
- ritonavir, a medicine used in the treatment of HIV infections
- phenytoin, a medicine used to treat epilepsy
- rifampicin
- St John's wort, a herbal remedy
- Statins, medicines used to lower cholesterol levels

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Procur.

How to take Procur

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

Men:**Prostate Cancer**

The usual total daily dose is 100-300 mg of Procur in divided doses. Your doctor may request you to take Procur with other medicines and/or change your dose during treatment.

Control sexual desire

The usual dose is 50 mg of Procur twice daily and may be increased. Once the desired effect is achieved, your dose may be gradually lowered.

Women:**Childbearing age****If you are pregnant, do not take Procur.**

Therefore, pregnancy must be excluded before starting treatment.

The usual dose is 50 mg of Procur taken once daily for 10 days per month. This dose may be increased in severe symptoms.

If you are of a childbearing age you should commence your tablet on the 1st day of the cycle (= 1st day of bleeding). If you have no menstrual periods, your treatment can commence immediately. In this case, the first day of treatment is to be regarded as the 1st day of the cycle.

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

The length of use depends on the severity of your symptoms and the extent of response to treatment. Your doctor should re-evaluate the treatment periodically as long-term use should be avoided.

Postmenopausal or have had a hysterectomy

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

How to take it

Swallow the tablets whole with some liquids after meals.

When to take it

Take your medicine after a meal, at about the same time each day.

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

How long to take it

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

This medicine helps you control your condition but does not cure it. Therefore, you must take it every day.

If you forget to take it

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

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

If you are also taking oral contraceptive and more than 12 hours elapsed from the time Procur was due to be taken, note that contraceptive protection in this cycle may be reduced. If bleeding fails to occur after this cycle, there is a risk of pregnancy. Your doctor may need to check whether you are pregnant before you can continue treatment.

While you are taking Procur

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Procur.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you feel shortness of breath, tell your doctor.

Shortness of breath has been reported in patients taking this medicine at high doses.

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

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 Procur 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 Procur.

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

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.

Things you must not do

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

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

Things to be careful of

Be careful driving or operating machinery until you know how Procur affects you. It may cause tiredness and can impair the ability to concentrate.

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

Procur from working as well as it should in reducing abnormal sex drive.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Procur.

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

Side effects

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

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

Do not be alarmed by this list of possible adverse 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:

Men:

- decreased sex drive (decreased libido)
- inability to obtain or maintain an erection
- breast enlargement

Men- Other adverse effects include:

- reduced sperm count
- thinning of the bones (osteoporosis)

Women:

- decreased or increased sex drive
- a feeling of tension in breasts
- menstrual cycle irregularity, spotting

Both:

- weight decrease or increase
- tiredness, fatigue
- headache
- depressive mood
- nausea and other gastrointestinal complaints
- hot flushes, sweating
- shortness of breath

If any of the following happen, stop taking Procur and 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; hives; fainting

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Procur. You may need urgent medical attention or hospitalisation. These side effects are very rare.

- general malaise, fever, nausea, vomiting, loss of appetite, general itching, yellowish skin and eyes, light-coloured stools and dark urine.
- severe upper abdominal pain
- swelling of the calf or leg, chest pain, shortness of breath or sudden feeling of weakness.
- sudden severe headache, loss of vision, loss of coordination, weakness in arms or legs.

These may be serious side effect of Procur. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking Procur

Storage

Keep your tablets in the bottle or blister pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

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

Do not store Procur in the bathroom or near a sink. Do not leave it in the car or on a windowsill. 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Procur 50 mg – 50 mg tablets are white to off-white, round, flat, tablets having a score and embossed 50 on one side and plain on the other.

Procur 100 mg – 100 mg tablets are white to off-white, capsule shaped tablets having a score on one face and embossed 100 on the other.

Ingredients

Active ingredient(s):
cyproterone acetate

Inactive ingredients:
croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone, lactose monohydrate

Sponsor details

Procur is supplied in New Zealand by:
Douglas Pharmaceuticals Ltd
P O Box 45 027
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New Zealand
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16 June 2020
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