

Consumer Medicine Information

This leaflet answers some of the common questions about Procur 100 tablets. 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 100 tablets against the benefits the medicine is expected to 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.

Identification

Procur 100 is the brand name for tablets containing 100 mg of the antiandrogenic substance, cyproterone acetate as the active ingredient.

As well as its active ingredient, Procur 100 contains lactose, cellulose-microcrystalline, croscarmellose sodium, povidone and magnesium stearate.

What is Procur 100 used for and how does it work?

Procur 100 is an antiandrogenic hormone medication containing the active ingredient cyproterone acetate which is used to treat cancer of the prostate gland. 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.

Cancer of the prostate gland generally requires androgenic hormones to grow. Procur 100 works in two ways. Firstly it stops the androgen hormones (testosterone) present in your body from being able to attach to the cancer cells. Secondly by an effect on the hormonal mechanisms that control androgen production by the body, it decreases the amount of androgen hormone present in your blood stream.

Procur 100 is only available on a doctor's prescription.

There is no evidence that Procur 100 tablets are addictive

Before you take Procur 100

Procur 100 can rarely cause severe damage to your liver, resulting in jaundice and hepatitis. Your doctor should perform a blood test to check your liver before starting you on Procur 100 and again if liver disease is suspected. Yellowing of the skin/eyes, abdominal pain or swelling and darkening of the urine should be all reported immediately to your doctor.

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. Tell your doctor if you have upper abdominal complaints. Procur 100 has been observed to attach itself to the genetic material in animal and human liver cells. However an increase in liver cancers has not been seen in humans.

Procur 100 tablets cause 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. Male patients may need to have a sperm count.

Before you start to take Procur 100 tablets

Tell your doctor if:

- You are allergic to any other medicines or other substances such as foods, dyes or preservatives or any of the ingredients in the tablet.
- You have in the past suffered from blood clots in the leg, stroke or heart attack.
- You have sickle-cell anaemia.
- You have severe diabetes that has damaged your blood vessels.
- You have suffered from any disease or tumour of your liver.
- You have suffered from severe chronic depression.
- You have Dubin-Johnson syndrome or Rotor syndrome.
- You are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

If you are not sure whether you should be taking Procur 100 tablets, talk to your doctor.

Do not take Procur 100 tablets if:

- The expiry date on the pack has passed. If you take this medicine after the date has passed it may have no effect at all, or worse, an entirely unexpected effect.
- The packaging is torn or shows signs of tampering or the tablets do not look quite right.

Do not give Procur 100 tablets to children.

Taking other medicines

If you are taking other medicines you must tell your doctor. This includes medicine that you can buy without a prescription from a pharmacy, supermarket or a health food shop. Some medicines are affected by others. Your doctor or pharmacist will be able to tell you what you should do when you have to take other medicines while you are on Procur 100.

How to take Procur 100 tablets

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

The dosage of Procur 100 will be determined by your doctor.

Swallow the prescribed dose with a glass of water after a meal.

If you forget to take it

If it is almost time to take your next dose, skip the dose that you have missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, then go back to taking your tablets as usual.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to the casualty department at your nearest hospital, if you think that you or anyone else may have taken too many Procur 100 tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

While you are taking Procur 100 tablets

Things you must do

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Procur 100 tablets.

You may be required to have regular tests for liver, blood or other body functions.

Things you must not do

Do not give Procur 100 tablets to anyone else, even if they have the same condition as you.

Do not use Procur 100 tablets to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Procur 100 tablets affect you. Procur 100 may cause drowsiness and loss of concentration in some people.

Side Effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking Procur 100 tablets, even if you do not think that the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Procur 100 tablets can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

Infertility and impotence are expected effects of Procur 100 and cannot generally be avoided. The most common side effect that may occur is tiredness and loss of concentration which may affect your ability to drive or operate machinery. Procur 100 may occasionally result in gynaecomastia (swelling of the breast area which is sometimes also associated with tenderness or sensitivity of the breast area to touch), changes in body weight, diminished libido, nausea, allergy, headache, depressive moods, shortness of breath and blood clotting (which may lead to a clot on the lungs, stroke or heart attack).

This is not a complete list of all possible side effects.

Tell your doctor if you notice any other effects while using Procur 100 tablets.

After Using Procur 100 tablets

Storage

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

Keep Procur 100 tablets in a cool dry place where the temperature stays below 30°C.

Do not store Procur 100 tablets or any other medicine in the bathroom or near a sink.

Do not leave Procur 100 tablets in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Procur 100 tablets where children can not reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date.

Ask your pharmacist what to do with any tablets left over.

Product Description

Procur 100 are capsule shaped tablets with '100' engraved on one face and a break line on the other face.

Procur 100 is presented in packs containing 50 tablets.

Australian Registration Number:
Procur 100 blister pack AUST R 101532

Sponsor

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