

EULEXIN(R)

Flutamide

Consumer Medicine Information

What is in this leaflet

The name of your medicine is EULEXIN. It contains the active ingredient called flutamide.

This leaflet answers some common questions about EULEXIN.

It does not contain all of 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 EULEXIN against the benefits this 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 want to read it again.

What EULEXIN is used for

EULEXIN is used in combination with medical castration to treat prostate cancer.

The Prostate Gland

The prostate gland is a walnut-sized gland that surrounds the upper part of the urethra. The urethra is a tube through which urine and sperm exit through the tip of the penis.

The main job of the prostate gland is to produce fluid that nourishes and transports sperm. The gland is vulnerable to two common but unrelated medical problems -

enlargement and cancer.

Cancer of the Prostate

Prostate cancer is the most common cancer among Australian men.

About 1 in every 10 men will develop the disease in his lifetime.

The causes of prostate cancer are unknown but the disease is often responsive to treatment.

Who is at Risk?

Prostate cancer is more common in older men; 80% of men who develop prostate cancer are diagnosed when they are over the age of 65. However, some men develop the disease when they are younger.

What is Maximal Androgen Blockade?

Prostate cancer cells need androgens (male hormones) to grow. There are two sources of androgens in your body: the testes and the adrenal glands (small glands that sit on top of your kidneys). Maximal androgen blockade which combines castration and a medicine called an antiandrogen, is designed to prevent the androgens from both sources reaching and nourishing the cancer cells.

Castration stops the production of testosterone by the testes. Castration can be accomplished either surgically or medically. Surgical castration, called an orchidectomy is the actual removal of the testes. Medical castration involves taking hormonal drugs known as luteinising hormone-releasing hormone (LHRH) agonists which stop the testes from producing testosterone. Two examples of LHRH agonists are

Lucrin (leuprolide) and Zoladex (goserelin acetate). LHRH agonists are given as monthly injections.

While castration "shuts off" the production of testosterone by the testes, it does nothing to stop the androgens produced by the adrenal glands from continuing to nourish the cancer cells.

How EULEXIN works:

To block the adrenal androgens from reaching the cancer cells, your doctor has prescribed EULEXIN, an antiandrogen. EULEXIN is used in combination with medical castration. The combination of medical castration and EULEXIN blocks androgens from all sources; this is called maximal androgen blockade.

Your doctor, however, may prescribe EULEXIN for another purpose.

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

Before you take EULEXIN

When you must not take it:

Do not take EULEXIN if you are allergic to:

- * flutamide or any of the ingredients listed at the end of this leaflet.

Do not take EULEXIN if you have serious liver problem

Do not take EULEXIN after the expiry date (EXP) printed on the pack.

Do not take EULEXIN if packaging is torn or shows sign of tampering.

Before you start to take it:

You must tell your doctor if:

1. you are allergic to:
 - * any other medicines or any food, dyes or preservatives
2. you have any other medical conditions or health problems.
3. you are pregnant or breast feeding

EULEXIN is for use by men. It should not be taken by women who are pregnant or breast feeding.

Taking other medicines:

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. There may be some interference between EULEXIN and some other medicines, including:

- * Oral anticoagulant such as warfarin, a medicine used to prevent blood clots.
- * Theophylline, used for asthma

How to take EULEXIN

How much to take

Take one tablet by mouth three times a day exactly as directed by your doctor.

When to take it

Taking EULEXIN every 8 hours is the best way of making sure the therapy will block the androgens in your body.

Take one tablet when you first get up, one in the afternoon and one at bedtime. EULEXIN can be taken with or without food.

Do not use meals as a reminder to

take EULEXIN because meals are not normally 8 hours apart.

How long to take it

Continue to take EULEXIN regularly, even when you begin to feel better.

Do not stop taking this medicine without first checking with your doctor.

If you forget to take it

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 it as you would normally.

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

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

If you take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (Ph 13 11 26) for advice, or go to casualty at your nearest hospital, if you think you or anyone else may have taken too much EULEXIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are taking EULEXIN

Things you must do:

Your doctor may want you to have your blood tested occasionally during your therapy.

Use EULEXIN exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking EULEXIN.

Tell your doctor or pharmacist that you are taking EULEXIN if you are about to be started on any new medicines.

Things you must not do:

Do not take this medicine to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of:

EULEXIN generally does not cause any problems with your ability to drive a car or operate machinery.

However, make sure you know how you react to EULEXIN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Side effects

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

All medicines have side effects. Sometimes they are serious, most of the time they are not. Although not all of these side effects may occur, if they do occur they may need medical attention.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor immediately if you notice any of the following symptoms. These may indicate liver disorder, which has been reported very rarely with EULEXIN.

- * itching of the skin
- * dark urine (amber or yellow-green urine is not a cause for concern)

- * persistent lack of appetite
- * yellow eyes or skin
- * tenderness in the right upper stomach
- * constant tiredness or "flu-like" symptoms.

Patients receiving the combination of EULEXIN plus medical castration may have:

- * diarrhoea
- * hot flushes (sudden sweating and feelings of warmth)
- * increased breast size
- * nausea
- * vomiting

Unwanted effects that may occur rarely include:

- * bleeding or bruising more than normal
- * loss of appetite
- * injection site irritation or rash
- * swelling of feet or lower legs
- * shortness of breath
- * muscle ache or twitching
- * high blood pressure
- * liver damage or brain coma from liver illness
- * yellow discolouration of the skin or eyes due to failure to remove bile

Unwanted effects that may occur very rarely include:

- * difficult or labored breathing
- * feeling fatigued
- * excessive thirst and urination
- * unusual weight loss or weight gain
- * nausea and vomiting
- * slow healing cuts or infection
- * blurred vision
- * always feeling hungry
- * headaches and feeling dizzy
- * mood swings
- * leg cramps, tingling/numbness in hands and/or feet

Tell your doctor or pharmacist if any of these occur.

In general, patients will experience few additional effects when EULEXIN therapy is added to medical castration.

In the largest study conducted to date, patients treated with EULEXIN plus medical castration experienced similar side effects as patients treated with medical castration alone, except patients receiving EULEXIN had a higher incidence (about 12%) of diarrhoea.

The following tips may help if you are experiencing diarrhoea:

- * drink plenty of fluids
- * cut down on dairy products
- * try eating smaller food portions
- * eat more carbohydrates
- * in consultation with your physician, you may also try taking medication to manage diarrhoea.

Since a variety of medications can cause diarrhoea, it is important to tell your physician about all the medicines you take, including those that are non-prescription.

Any therapy that stops the production of male hormones, such as medical or surgical castration, will affect your sex drive. However, the addition of EULEXIN to medical castration will not add to this effect. It is important to remember that the reduction of androgen levels may make erection more difficult. If you experience problems, please ask your doctor about available treatment options.

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

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using EULEXIN

Storage

Keep it where young children cannot reach it.

Store the tablets at room temperature in a dry place, away from heat and direct light.

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

EULEXIN is a round, pale yellow tablet. It is available in bottles of 100 tablets.

Ingredients

Each tablet contains:

- * flutamide 250 mg
- * lactose anhydrous
- * sodium lauryl sulfate
- * microcrystalline cellulose
- * pregelatinised maize starch
- * silicon dioxide
- * magnesium stearate

Manufacturer

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