

EULEXIN® (flutamide) Capsules

Important information for patients taking EULEXIN® (brand of flutamide) capsules.

Read this information carefully each time your prescription is refilled because there may be new information available. This summary does not tell you everything you need to know about EULEXIN therapy. Your doctor is the best source of information about your treatment. Ask your doctor about questions you have.

What is EULEXIN therapy?

EULEXIN, in combination with other therapies, is a treatment option for men with some types of prostate cancer.

Prostate cancer results from the abnormal growth of prostate cells. Medical scientists do not know exactly what causes the abnormal cells, but age, environment, and genetics are important factors. Male hormones ("androgens") cause the cancer to grow. The cancer growth can be slowed down by blocking the effect of androgens.

The EULEXIN product is used together with an injection called "LH-RH agonist", as a combined treatment called "total androgen blockade". The goal of this treatment is to reduce androgen levels and to block the effect of androgen on the tumor. The LH-RH agonist reduces androgen levels. EULEXIN therapy blocks the effect of androgen on the tumor.

Who should not take the EULEXIN product?

You should not take EULEXIN Capsules if you have liver problems or if you are allergic to it. EULEXIN Capsules are for use **only** in men, therefore women should not take EULEXIN Capsules.

Are there important risks I should know about EULEXIN therapy?

Some men taking the EULEXIN product had liver injury and needed to be hospitalized. In rare cases, men died because of liver failure while they were taking EULEXIN. In about half of these cases, the liver failure occurred in the first 3 months that they were taking EULEXIN.

Because the EULEXIN product may cause liver failure, **it is very important that you have all blood tests recommended by your doctor.** These tests help identify whether you are having liver problems. A recommended schedule for these blood tests is:

- before starting EULEXIN treatment.
- every month for the first 4 months of therapy.
- periodically after the first 4 months.

In addition, you should call your doctor right away if you have any of the following signs or symptoms:

- loss of appetite.
- nausea and vomiting.
- stomach or abdominal pain.
- fatigue (feeling extremely tired).
- flu-like symptoms (muscle aches, soreness).
- brown urine.
- jaundice (yellowing of the skin or whites of the eyes).

These may be signs of liver failure.

How should I take EULEXIN capsules?

Take your EULEXIN capsules as your doctor has prescribed. The usual dosing is 2 capsules every 8 hours.

Your doctor will determine whether EULEXIN therapy is right for you based on many different factors. These include how large your tumor is, how far it

has spread and your physical condition. In addition to EULEXIN, you may be getting other treatments, including regular injections of LH-RH agonist or radiation therapy. Do not stop or interrupt any treatment without consulting your healthcare professional.

If you miss a dose of EULEXIN capsules, simply continue therapy with your next scheduled dose. Do not try to make up for it by taking extra capsules.

Can I take other medicines?

If you are taking any other medicines, especially warfarin (a blood-thinning drug), tell your doctor before beginning EULEXIN therapy.

What are the other possible side effects of taking EULEXIN capsules?

In a medical study, when EULEXIN was taken together with an LH-RH agonist, the most common side effects were hot flashes, loss of sex drive (libido) and impotence. In addition, some men had diarrhea, nausea or vomiting, and breast enlargement.

In another medical study, when the EULEXIN product was taken together with goserelin acetate (an LH-RH agonist) and radiation therapy, the side effects of EULEXIN were about the same as when radiation therapy was given alone. These included hot flashes, diarrhea, nausea and skin rash.

What can I do if I get diarrhea?

If you experience moderate diarrhea due to EULEXIN capsules, the following advice may help:

- drink plenty of fluids.
reduce your intake of dairy products (for example, milk, cheese, yogurt).
- increase your intake of whole grains, fruits, and vegetables.
- stop laxative use.
- take non-prescription anti-diarrheal medicines.

If your diarrhea continues or it becomes severe, contact your doctor right away.

Are there any other lab tests my doctor will be performing?

Your doctor may perform other regular tests (such as the PSA blood test) to ensure that your body is responding to treatment. Ask your doctor if you have any questions about how your EULEXIN therapy is being monitored.

Where can I get further support?

Patients taking EULEXIN capsules have access to Schering's COMMITMENT TO CARE™, which can help you find financial reimbursement for your EULEXIN therapy. The following services are available (1-800-521-7157):

- research into reimbursement options.
- advice on how to obtain reimbursement.
- support through Schering's Indigent Patient program.
- access to flexible payment programs.

Please ask your doctor about any questions concerning prostate cancer or EULEXIN therapy, or you can also ask for a more detailed leaflet that is written for healthcare professionals.

