

## INFORMATION FOR THE CONSUMER

- 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 EUFLEX (flutamide) therapy. Your doctor is the best source of information about your treatments. Ask your doctor about questions you have.

### What is EUFLEX Therapy?

**EUFLEX** tablet, 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.

Prostate-specific antigen (PSA) is a marker used for monitoring cancer progression and response to therapy. PSA can be measured from a blood sample. PSA levels are usually elevated in cancer progression and low when responding to therapy.

**EUFLEX** is used together with an injection called “LHRH 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 LHRH agonist reduces androgen levels. **EUFLEX** therapy blocks the effect of androgen on the tumor.

### Who Should Not Take EUFLEX?

You should not take **EUFLEX** tablets if you have liver problems or if you are allergic to it. Women should not take **EUFLEX** tablets.

### Important Risks You Should Know About EUFLEX Therapy

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

Because **EUFLEX** can 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 **EUFLEX** treatment
- every month for the first 4 months of therapy
- periodically after the first 4 months

Also, your doctor will be monitoring your PSA blood concentrations during treatment. If PSA values remain high or start to increase, it is likely that your **EUFLEX** and LHRH agonist treatment will be discontinued. Your PSA values will continue to be monitored for 6 to 8

weeks after discontinuing treatment to see if the PSA values go down, and whether other forms of treatment should be considered.

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)

### **How to Take EUFLEX**

- Take your **EUFLEX** tablets as your doctor has prescribed.

- Your doctor will determine whether **EUFLEX** 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 **EUFLEX** tablets, you may be getting other treatments including regular injections of LHRH agonist or radiation therapy. Do not stop or interrupt any treatment without consulting your healthcare professional.

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

### **Taking Other Medicines**

If you are taking any other medicines, tell your doctor before beginning **EUFLEX** therapy. Euflex is known to interact with anti-coagulant medication as well as drugs containing theophylline as an active ingredient.

### **Other Possible Side Effects of Taking EUFLEX Tablets**

In a medical study, when **EUFLEX** tablets were taken together with an LHRH 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 **EUFLEX** was taken together with goserelin acetate (an LHRH agonist) and radiation therapy, the side effects of **EUFLEX** were about the same as when radiation therapy was given alone. These included hot flashes, diarrhea, nausea, and skin rash.

### **What to do when you get Diarrhea**

If you experience moderate diarrhea due to **EUFLEX** tablets, 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 nonprescription antidiarrheal medicines

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

**Other Laboratory Tests Your Doctor May be Performing**

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

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