Flutamide capsules are indicated for use in combination with LHRH-agonists for the treatment of stage D2 prostatic carcinoma.

The goal of this treatment is to reduce androgen levels and to block the effect of androgens on the tumor. The LHRH agonist reduces androgen levels. Flutamide therapy blocks the effect of androgen on the tumor.

Who should not take the flutamide product?

You should not take flutamide capsules if you:

- Have liver problems or if you are allergic to it.

Flutamide capsules are for use only in men; therefore women should not take flutamide capsules.

Important information for patients taking flutamide capsules.

Some men taking the flutamide product had liver injury and needed to be hospitalized. In rare cases, men died because of liver failure while they were taking flutamide capsules. Flutamide capsules are for use only in men; therefore women should not take flutamide capsules.

Are there any important risks I should know about flutamide therapy?

Some men taking the flutamide product had liver injury and needed to be hospitalized. In rare cases, men died because of liver failure while they were taking flutamide capsules. Flutamide capsules are for use only in men; therefore women should not take flutamide capsules.

Before starting flutamide treatment, you should discuss all of the important information with your doctor.

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).

This may be signs of liver failure.

How should I take flutamide capsules?

Take your flutamide capsules as directed by your doctor.

Your doctor will determine whether flutamide therapy is right for you based on many different factors. 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 flutamide therapy. Your doctor is the best source of information about your treatment. Ask your doctor about questions you have.

What is flutamide therapy?

Flutamide capsules are 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 effects of androgens.

The flutamide-product is used together with an injection called "LHRH agonist," as a combined treatment called "total androgen blockade."
Can I take other medicines?

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

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

In a medical study, when flutamide capsules 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 the flutamide product was taken together with goserelin acetate (an LHRH agonist) and radiation therapy, the side effects of flutamide therapy 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 flutamide 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 nonprescription antidiarrheal medicines.

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

Are there any other lab tests my doctor will do before starting flutamide therapy?

How should I take flutamide capsules?

The recommended dosage is 2 capsules 3 times a day at 8-hour intervals for a total of 6 capsules each day.

In SGOT. The single dose of flutamide ordinarily associated with symptoms of over-reactions reported included gynecomastia, breast tenderness, and some increases in SGOT.

Effective antidiarrheal agents include opium, barbiturates, or other preparations, such as Unisom or Kaopectate. Unisom contains diphenhydramine (an antihistamine) and dimenhydrinate (an antiemetic) that may help control diarrhea.

It is important to have your doctor determine if other medicines can be safely taken together with flutamide capsules.

If your doctor determines that other medicines can be safely taken with flutamide capsules, make sure your doctor is aware of the medicines you are taking, including prescription drugs, nonprescription drugs and herbal products. Your doctor may need to change the dose or schedule of the other medicine.

In any case, do not take any other medicine unless your doctor tells you to do so.

Before starting flutamide therapy, your doctor may perform one to two blood tests:

• Periodically after the first 4 months.
• Before starting flutamide therapy.

Your doctor may perform other routine tests (such as the PSA blood test) to ensure that your body is responding to treatment. Ask your doctor if he or she has any questions about your treatment.

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

Manufactured by: PAR PHARMACEUTICAL

Chestnut Ridge, NY 10977

Revised: 11/16 OS753-01-1-04

OVDOSAGE

In animal studies with flutamide alone, signs of overdose included hypoglycemia, hypothermia, tremors, ataxia, anorexia, diarrhea, and tremors.

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