

# INFORMATION FOR THE PATIENT

**DRUGS-ABOUT.COM**

## APO-FLUTAMIDE

### Flutamide Tablets

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

#### **WHAT IS APO-FLUTAMIDE THERAPY**

Apo-Flutamide tablets, 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.

Apo-Flutamide 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 tumour. The LHRH agonist reduces androgen levels. Apo-Flutamide therapy blocks the effect of androgen on the tumour.

#### **WHO SHOULD NOT TAKE APO-FLUTAMIDE**

You should not take Apo-Flutamide tablets if you have liver problems or if you are allergic to it. Women should not take Apo-Flutamide tablets.

#### **IMPORTANT RISKS YOU SHOULD KNOW ABOUT APO-FLUTAMIDE THERAPY**

In some patients with prostate cancer that has spread, antiandrogens such as flutamide may promote, rather than inhibit the growth of cancer. A decrease in PSA and/or clinical improvement have been observed when the antiandrogen was discontinued. If you experience increasing PSA levels while on flutamide, it is recommended that the flutamide be discontinued under your doctor's supervision, and your condition be monitored for 6-8 weeks before any decision is made to proceed with other prostate cancer therapy.

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

Because Apo-Flutamide 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:

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- 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)

#### **HOW TO TAKE APO-FLUTAMIDE**

Take your Apo-Flutamide tablets as your doctor has prescribed.

Your doctor will determine whether Apo-Flutamide therapy is right for you based on many different factors. These include how large your tumour is, how far it has spread, and your physical condition. In addition to Apo-Flutamide 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 health care professional.

If you miss a dose of Apo-Flutamide 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, especially warfarin (a blood-thinning drug), tell your doctor before beginning Apo-Flutamide therapy.

#### **OTHER POSSIBLE SIDE EFFECTS OF TAKING APO-FLUTAMIDE TABLETS**

In a medical study, when flutamide 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 flutamide was taken together with goserelin acetate (an LHRH agonist) and radiation therapy, the side effects of flutamide 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 Apo-Flutamide 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 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 Apo-Flutamide therapy is being monitored.

Please ask your doctor about any questions concerning prostate cancer or Apo-Flutamide therapy, or you can ask for a more detailed leaflet that is written for health care professionals.

#### **WHO MANUFACTURES APO-FLUTAMIDE**

Apotex Inc.  
150 Signet Drive  
Weston, Ontario  
M9L 1T9

#### **REMINDERS:**

**This medicine has been prescribed only for you. Do not give it to anybody else.**

***If you require any further information or advice please consult your doctor or pharmacist.***