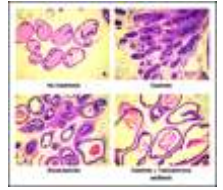
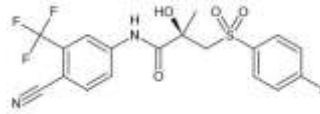


Rx BICALUTAMIDE

(Bicalutamide is an oral medication that is used for treating cancer of the prostate)



GENERIC NAME: bicalutamide

DRUG CLASS AND MECHANISM

Bicalutamide is an oral medication that is used for treating cancer of the prostate. It belongs to a class of drugs called anti-androgens which includes flutamide (Eulexin) and nilutamide (Nilandron). Androgens (an example of which is testosterone) are hormones that are produced and released by the adrenal glands. They are responsible for supporting (stimulating) tissues that primarily are thought of as male, for example, the male prostate gland. Male traits that also are influenced by androgens include facial and body hair and small breasts. Anti-androgens prevent the action of androgens by blocking the receptors for androgens on the cells of tissues, for example, the cells of the prostate gland. In addition to normal prostate cells, androgens also have been shown to stimulate the growth of cancer cells within the prostate. Bicalutamide is thought to prevent the growth of prostate cancer by blocking the effects of androgens on the cancer cells. Bicalutamide was approved by the FDA in 1995.

PRESCRIPTION: yes

PREPARATIONS: Bicalutamide is available as a 50mg tablet.

PRESCRIBED FOR

Bicalutamide is used in combination with another medication, a gonadotrophin hormone releasing factor, to treat advanced prostate cancer.

DOSING

Bicalutamide should be taken as one 50mg tablet in the morning or the evening at the same time each day. It may be taken with or without food. Once bicalutamide therapy has begun, it should not be interrupted or stopped without consulting a physician.

DRUG INTERACTIONS

Bicalutamide may interact with warfarin (Coumadin). Therefore, the dose of Coumadin may need to be adjusted.

USES

Bicalutamide is used to treat prostate cancer that has spread to other areas of the body. It is used in combination with hormone treatment. This medication works by blocking the action of male hormones in the prostate, slowing growth of the tumors. This medication should not be used in women or children.

HOW TO USE

Take this medication by mouth, usually once a day in the morning or evening, with or without food, or as directed by your doctor. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. The dosage is based on your medical condition and response to therapy. Do not increase your dose or take this medication more often without your doctor's approval. Your condition will not improve any faster, and the risk of serious side effects may be increased. Since this drug can be absorbed through the skin, women who are pregnant or who may become pregnant should not handle this medication.

SIDE EFFECTS

Flushing and sweating (hot flashes), body aches and pains, breast swelling/tenderness/pain, headache, dizziness, drowsiness, trouble sleeping, weakness, hair loss, weight changes, constipation, diarrhea, stomach upset, gas, nausea, vomiting, and loss of appetite may occur. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: decreased sexual ability/desire, vision changes, numbness/tingling of the hands or feet, swelling of the arms/legs, unusual or easy bleeding/bruising, change in the amount of urine, painful urination, signs of infection (e.g., fever, chills, persistent sore throat), trouble breathing, persistent cough, mental/mood changes (e.g., anxiety, depression). Seek immediate medical attention if any of these rare but very serious side effects occur: chest pain, jaw/left arm pain. Rarely, bicalutamide may cause growth of other types of tumors. Consult your doctor immediately if new lumps or growths occur. This medication may rarely cause serious (possibly fatal) liver disease. Seek immediate medical attention if any of these side effects occur: dark urine, yellowing of the eyes/skin, unusual tiredness, severe stomach/abdominal pain, persistent nausea/vomiting. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness,

trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking bicalutamide, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, diabetes. When higher doses (150 milligrams per day) of this medication are used in patients with early-stage localized prostate cancer, more deaths have occurred than in patients whose doctors decided to monitor them closely before treating with this medication. Ask your doctor for more details and discuss the risks and benefits of your treatment. This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. To minimize these effects and flushing of the face, limit alcoholic beverages. Bicalutamide should not be used in women or children. It must not be used in a woman who may be pregnant or breast-feeding. This medication may cause harm to an unborn or breast-feeding baby.

DRUG INTERACTIONS

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop, or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: warfarin. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

For the best benefits, it is important to take this medication as directed. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA), or 1-800-668-1507 (Canada).

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

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