Ketoconazole (Nizoral®)

**Pronounced:** kee-toe-KOE-na-azole

**Classification:** Antifungal Agent

### About Ketoconazole (Nizoral®)

Ketoconazole is typically used as an antifungal medication used to treat fungal infections. However, it can be used in the treatment of advanced prostate cancer, although it is not approved by the FDA for this use. The information provided here focuses on the use of ketoconazole to treat prostate cancer. Ketoconazole can inhibit the production of steroids in your body, including testosterone. The inhibition of the production of steroids can slow down and possibly stop the progression of prostate cancer.

### How to Take Ketoconazole

Ketoconazole is a tablet that should be taken orally (by mouth). The dosage and number of times per day you should take it varies depending upon the reason you are taking ketoconazole. Follow the prescriber’s directions for taking this medication. You should avoid drinking recreational alcohol or ingesting products made with alcohol (some mouthwashes, cough syrups, etc) while on this medication because it can increase the risk of liver damage. Some patients have reported having allergic reactions to this medication ranging from mild side effects like itching, to very serious side effects including anaphylactic reaction. If you have any shortness of breath, difficulty breathing, chest pain, rash, flushing or itching notify your provider immediately or call 911.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The levels of many medications in your blood can be affected by ketoconazole, just as other medications can affect the level of ketoconazole in your blood. For example, ketoconazole can increase the plasma concentration of oral midazolam (Versed), triazolam (Halcion), and alprazolam (Xanax), which can increase the severity of lethargy commonly caused by these medications. Antacids and proton pump inhibitors can decrease the plasma concentration of ketoconazole. It is very important to notify your provider of all medications, both prescribed and over the counter, and any herbal or holistic supplements you are taking. If you have any questions regarding interactions, you can also ask your pharmacist.

### Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). If you prefer to use a pillbox, discuss this with your oncology pharmacist. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash. Keep containers out of reach of children and pets.

### Where do I get this medication?

Ketoconazole is available through mail order and retail pharmacies. Your oncology team will work with you to identify an in-network pharmacy for distribution of this medication.

### Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying
individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects

There are a number of things you can do to manage the side effects of ketoconazole. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Liver Toxicity

This medication can cause liver toxicity, which your healthcare provider may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.

Heart Problems

This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Notify your healthcare provider right away if you feel abnormal heartbeats or if you feel dizzy or faint.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Diarrhea

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Headache and Abdominal Pain

Your doctor or nurse can recommend medication and other strategies to relieve pain.

Less common, but important side effects can include:

- **Breast Tenderness or Increase in Breast Tissue:** An increase in breast tissue (gynecomastia) or breast tenderness may develop due to the changes in testosterone levels. Your healthcare team can suggest medications to relieve the tenderness. In rare cases, radiation can be given to relieve severe tenderness.

- **Allergic Reactions:** Some patients have reported having allergic reactions to this medication ranging from mild side effects like itching, to very serious side effects including anaphylactic reaction. If you have any shortness of breath, difficulty breathing, chest pain, rash, flushing or itching notify your provider immediately or call 911.

- **Adrenal Insufficiency:** Adrenal insufficiency (inadequate function of the adrenal gland) is a rare but serious side effect of taking this medication. Symptoms are not very specific, but can include nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. It is important to contact your care provider if you experience any of these side effects.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not father a child while on this medication. Effective birth control is necessary during treatment, even if you believe you are not producing sperm. You may want to consider sperm banking if you may wish to have a child in the future. Discuss these options with your oncology team. Women should not breastfeed while taking this medication.
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