

Apalutamide (Erleada®)

Pronounced: a-pa-LOO-ta-mide

Classification: Anti-Androgen Receptor

About Apalutamide (Erleada®)

Most prostate cancers need the male hormone testosterone to grow. Testosterone is an androgen (type of hormone) produced by the testes and adrenal glands. Anti-androgen therapies work by blocking an enzyme necessary for the production of testosterone. Without testosterone, the cancer cells may either grow more slowly, or stop growing altogether.

How to Take Apalutamide

Apalutamide comes in tablet form. It should be taken once daily, swallowed whole, and can be taken with or without food. If you have trouble swallowing this medication you can mix the whole tablets with 4 ounces of apple sauce and stir. Wait 15 minutes and stir the mixture again. Wait another 15 minutes and stir the tablets and apple sauce until the tablets are well mixed with the apple sauce and there are no chunks. Eat all of the apple sauce. If you have not had a bilateral orchiectomy (removal of both testicles) this medication should be given with a gonadotropin-releasing hormone analog like leuprolide (Lupron®), gosarelin (Zoladex®) or triptorelin (Trelstar®).

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 blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: clopidogrel, gemfibrozil, itraconazole, ketoconazole, voriconazole, posaconazole, rifampin, clarithromycin, midazolam, omeprazole, warfarin, fexofenadine, phenytoin, tacrolimus and rosuvastatin, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

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). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon 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 apalutamide. 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:

Fatigue

<u>Fatigue</u> is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Rash

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

High Blood Pressure

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

Diarrhea

Your oncology care team can recommend medications to relieve <u>diarrhea</u>. Also, try eating <u>low-fiber</u>, 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 on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the <u>red cell count is low</u>, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your <u>WBC count can drop</u>, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F/38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- · Do not handle pet waste.
- Keep all cuts or scratches clean.

- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

High Cholesterol Level

This medication can cause high levels of cholesterol. You may be monitored for this using blood tests. There are no immediate symptoms of high cholesterol but when not treated appropriately it can lead to heart attack and stroke.

High Blood Sugar

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

High Potassium Level

This medication can cause a higher than normal potassium level (hyperkalemia) in the blood. You will have blood tests done to monitor for this. There are typically no symptoms of hyperkalemia but very high levels can cause heart palpitations, muscle pain, weakness and numbness.

Less common, but important side effects can include:

- Falls and Fractures: This medication can put you at an increased risk of falls and fractures. Your fall risk will be assessed and you may be ordered bone density assessments.
- **Seizures:** Although rare, this medication can cause seizures. You should notify your care team of any history of seizures, sudden loss of consciousness or new seizure.
- **Heart and Brain Issues**: Although rare, this medication can cause bleeding in the brain or blockage of arteries in the heart. If you have chest pain, shortness of breath, numbness or weakness on one side of the body or part of the body, trouble talking or seeing, dizziness, loss of balance, or trouble walking you should call your provider right away.

Sexual & Reproductive Concerns

This medication may affect your reproductive system, resulting in sperm production becoming irregular or stopping permanently. The desire for sex may decrease during treatment. You may want to consider sperm banking if you may wish to have a child in the future. However, you should not donate sperm during treatment or for 3 months after your last dose. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not father a child while on this medication. Condom use is necessary during treatment and for at least 3 months after treatment, even if you believe you are not producing sperm.

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