

For the Patient: Apalutamide Other names: ERLEADA®

- **Apalutamide** (a' puh loo" tuh mide) is a drug that is used to treat prostate cancer. It blocks the effect of testosterone which is a male sex hormone that may stimulate the growth of prostate cancer. Apalutamide is often used with another drug that lowers testosterone levels. It is a tablet that you take by mouth.
- Tell your doctor if you have ever had an unusual or allergic reaction to apalutamide before taking apalutamide.
- **Blood tests** and **blood pressure measurements** may be taken regularly during treatment.
- It is important to **take** apalutamide exactly as directed by your doctor. Make sure you understand the directions.
- You may **take** apalutamide with food or on an empty stomach.
- If you miss a dose of apalutamide, take it as soon as you can if it is within 12 hours
 of the missed dose. If it is more than 12 hours since your missed dose, skip the
 missed dose and go back to your usual dosing times.
- Other drugs such as gemfibrozil (LOPID®), ketoconazole (NIZORAL®), warfarin (COUMADIN®), and omeprazole (LOSEC®) may **interact** with apalutamide. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of apalutamide.
- Apalutamide may affect **fertility** in men. If you plan to have children, discuss this with your doctor before being treated with apalutamide.
- Apalutamide may damage sperm and may harm the baby if used during pregnancy.
 It is best to use birth control while being treated with apalutamide and for three
 months after the last dose of apalutamide. It is best for male patients to use a
 condom during sexual activity with a pregnant woman, and a condom plus one other
 effective birth control method during sexual activity with a woman who may become
 pregnant. Tell your doctor right away if your partner becomes pregnant.

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- **Store** apalutamide tablets out of the reach of children, at room temperature, away from heat, light, and moisture. Keep tablets in the original blister card packaging or in the pharmacy vial until needed.
- **Tell** doctors, dentists, and other health professionals that you are being treated with apalutamide before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur with apalutamide. Most people have little or no nausea.	To help nausea: • Drink plenty of fluids. • Eat and drink often in small amounts. Try the ideas in <i>Practical Tips to Manage</i>
Skin rashes may sometimes occur.	Nausea.* If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Diarrhea may sometimes occur.	 If diarrhea is a problem: Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.*
Constipation may sometimes occur.	 Exercise if you can. Drink plenty of fluids. Try ideas in Food Choices to Manage Constipation.*
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem:Elevate your feet when sitting.Avoid tight clothing.

SIDE EFFECTS	MANAGEMENT
Hot flashes (sudden sweating and feelings of warmth) sometimes occur with apalutamide.	 If hot flashes are troublesome: Take your apalutamide at bedtime. If night sweats interfere with sleep, try taking apalutamide in the morning. Some people find it helpful to avoid alcohol, spicy food, and caffeine (coffee, tea, colas, chocolate). Follow a regular exercise program. Try staying in a cool environment. Wear layers so that if you do experience a hot flash, the outer layers may be removed. Ask your doctor for more advice if your
Sugar control may commonly be affected in diabetic patients.	hot flashes continue to bother you. There may be medications available. Check your blood sugar regularly if you are diabetic.
You may sometimes have trouble sleeping.	 Talk to your doctor if you continue to have trouble sleeping. This will return to normal when you stop taking apalutamide.
Taste alteration may sometimes occur.	Try the ideas in Food Ideas to Cope with Taste and Smell Changes.*
Loss of appetite and weight loss sometimes occur.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
High blood pressure may sometimes occur.	 Your blood pressure will be checked during your visits to your doctor. You may be asked to check your blood pressure frequently between visits. Your doctor may give you medication if your blood pressure is high. Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose.
Tiredness and lack of energy may sometimes occur.	 Do not drive a car or operate machinery if you are feeling tired. Try the ideas in Fatigue/Tiredness – Patient Handout.*

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SIDE EFFECTS	MANAGEMENT
Increase in cholesterol or triglycerides. (one of the types of fat in the blood) commonly occurs.	 Discuss this with your doctor if you have: A history of heart disease. High blood pressure. High cholesterol or triglycerides. You may need to have your cholesterol level checked a few months after starting apalutamide.

^{*}Please ask your chemotherapy nurse or pharmacist for a copy.

STOP TAKING APALUTAMIDE AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Seizures or loss of consciousness.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of **bladder problems** such as changes in urination, painful burning sensation, presence of blood, or abdominal pain.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Abdominal pain.
- Increased clumsiness or falling.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Skin rash or itching.
- Signs of thyroid problems, such as unusual weight gain, feeling cold, or unusual tiredness or weakness.
- For diabetic patients: uncontrolled blood sugars.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR	

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