

## Apalutamide (Erleada)

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### About This Medicine

APALUTAMIDE (A puh LOO tuh mide) treats prostate cancer. It works by blocking the effect of testosterone and other hormones in your body, which may slow or stop cancer cells from spreading or growing. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Diarrhea (loose bowel movements)
- Tiredness
- Hot flashes or sudden skin flushing may happen. You may also feel warm or red.
- Decreased appetite (decreased hunger)
- Weight loss
- Risk of fall and fractures
- Pain in the joints
- Rash
- High blood pressure

**Note:** Each of the side effects above was reported in 10% or greater of people treated with apalutamide. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- Heart disease and risk of heart attack and stroke, which can be life-threatening
- Seizure. Common symptoms of a seizure can include confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. There are other less common symptoms of seizures. **If you or your family member suspects you are having a seizure, call 911 right away.**
- This medicine increases your risk of falls and fractures.

- Severe allergic skin reactions which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. Sometimes, you may have a rash along with problems with your organs, swollen lymph nodes, fever, and higher than normal white blood cells.
- Inflammation (swelling) and/or scarring of the lungs, which can be life-threatening. You may have a cough and/or trouble breathing.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## Important Information

- Do not donate sperm during your treatment or for 3 months after your cancer treatment.
- Do not stop taking apalutamide without first talking with your care team.
- You should avoid activities where a sudden loss of consciousness (passing out) could cause harm to yourself or others. Please speak to your care team for more information on precautions you may need to take.

## How to Take Your Medicine

- Swallow the medicine whole with or without food. Do not crush or split tablets. Take this medicine at the same time each day.
- If you have been prescribed a medicine to take with your apalutamide called a gonadotropin-releasing hormone analog, you should continue to take this medicine during your treatment with apalutamide. Speak with your care team if you have any questions.
- **For 240 mg tablets only:** If you have trouble swallowing the 240 mg tablet whole, you can mix the whole tablet in non-carbonated water, and then take it with either apple sauce, orange juice or water. Place the whole tablet in a cup with about 2 teaspoons (10 mL) of non-carbonated water to make sure it is completely covered in water. Do not crush or split the tablet. Wait 2 minutes, until the tablet is broken up and spread out, then stir the mixture. Add 2 tablespoons (30 mL) of either orange juice, apple sauce or additional water and stir the mixture. Swallow immediately. Rinse the cup with enough water to make sure the whole dose is taken and drink immediately. Do not store this medicine once it has been mixed with applesauce, orange juice or non-carbonated water.
- **For 60 mg tablets only:** If you have trouble swallowing 60 mg tablets whole, you can mix the whole tablets in non-carbonated water, and then take it with either apple sauce, orange juice or water. Place the whole tablets in a cup with about 4 teaspoons (20 mL) of non-carbonated water to make sure they are completely covered in water. Do not crush or split the tablets. Wait 2 minutes, until the tablets are broken up and spread out, then stir the mixture. Add 2 tablespoons (30 mL) of either orange juice, apple sauce or additional water and stir the mixture. Swallow immediately. Rinse the cup with enough water to make sure the whole dose is taken and drink immediately. Do not store this medicine once it has been mixed with applesauce, orange juice or non-carbonated water.
- Talk with your care team if you need to take your medicine through a feeding tube.
- **Missed dose:** If you miss a dose, take it as soon as you think about it if it is on the same day and continue with regular dosing schedule the following day.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.



- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove the desiccant packet. Protect from light and moisture. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you get a rash, do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.

## Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription or over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with apalutamide. Also, check with your care team before



starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Dry cough
- Wheezing and/or trouble breathing
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back, or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness
- Swollen lymph nodes in your neck and/or armpits
- Pain that does not go away or is not relieved by prescribed medicines
- Experience a fall

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can get your partner pregnant, use birth control while taking this medicine and for 3 months after the last dose. If your partner is pregnant, use a condom during sex. Tell your care team right away if you think your partner might be pregnant.
- **Breastfeeding warning:** It is not known if this medicine affects breastfeeding.



- **Fertility Warning:** This medicine can affect your ability to have children in the future. If you plan to have children, talk with your care team.

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