

Apalutamide (Erleada)

About This Medicine

Apalutamide is used to treat cancer. It is given orally (by mouth).

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 patients 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 medical 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.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical 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 doctor.
- You should avoid activities where a sudden loss of consciousness (passing out) could cause harm to yourself or others. Please speak to your doctor and/or nurse 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 doctor if you have any questions.
- **For 240 mg tablets only:** If you have difficulty 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 difficulty swallowing 60 mg tablets whole, you can mix whole tablets in 4 ounces of applesauce by stirring. Do not crush or split the tablets. Wait 15 minutes, stir the mixture. Wait another 15 minutes, stir the mixture until tablets are well mixed, and no chunks remain. Using a spoon, swallow the mixture right away. Rinse the container with 2 ounces of water and immediately drink the contents. Repeat the rinse with 2 ounces of water to ensure the whole dose is taken. Consume the mixture within one hour of preparation. Do not store this medicine once it has been mixed with applesauce.
- **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.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic 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.
- **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 nurse or your doctor 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 nurse or doctor 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 doctor's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash, do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist 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 doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptom

- 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.**
- 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
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 3 months after stopping treatment. If your partner is pregnant, use a condom during your cancer treatment. Let your doctor know right away if you think you may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk.
- **Fertility Warning:** In men, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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