

## Apalutamide (Erleada)

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### About This Drug

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

### Possible Side Effects

- Nausea
- 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
- 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. Not all possible side effects are included above.

### Warnings and Precautions

- Heart disease and risk of heart attack, 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 drug increases your risk of falls and fractures.

### Important Information

- Do not donate sperm during your treatment or for 3 months after your cancer treatment.

- 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 Medication

- Swallow the medicine whole with or without food. 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.
- If you have difficulty swallowing tablets whole, you can mix whole tablets in 4 ounces of applesauce by stirring. Do not crush the tablets. Wait 15 minutes, stir the mixture. Wait another 15 minutes, stir the mixture until tablets are dispersed, 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.
- If you vomit a dose, take your next dose at the regular time, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove the desiccant. 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 medication 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, 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.
- 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 Drug Interactions

- This drug 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 drug 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

- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- A headache that does not go away
- Blurry vision or other changes in eyesight
- 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.**
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- 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
- Weight gain of 5 pounds in one week (fluid retention)
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Pain that does not go away or is not relieved by prescribed medicines
- If you have a fall
- 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.**

- If you think you may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Apalutamide is not indicated for use in women. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 3 months after your cancer 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 drug passes into breast milk. Apalutamide is not indicated for use in women.
- **Fertility Warning:** In men, this drug 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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