

# Everolimus

**Care Team Contact Information:** \_\_\_\_\_

**Pharmacy Contact Information:** \_\_\_\_\_

**Diagnosis:** \_\_\_\_\_

- This treatment is used for many types of cancer and conditions not related to cancer.
- It may also be used for other reasons.

**Goal of Treatment:** \_\_\_\_\_

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Everolimus (eh-veh-ROH-lih-mus): Afinitor (uh-FIH-nih-tor), Afinitor Disperz (uh-FIH-nih-tor DIS-perz), Zortress (ZOR-tres)	Slows down or stops the growth of tumor cells by blocking specific proteins that helps them survive.	Tablet(s) or tablet(s) for oral suspension taken by mouth.

## Treatment Administration and Schedule

Your everolimus dosing instructions:

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- Everolimus comes in 4 tablet strengths: 2.5 mg, 5 mg, 7.5 mg and 10 mg; and 3 tablet for oral suspension strengths: 2 mg, 3 mg, and 5 mg. Your care team will tell you which tablets to take.
- Your dose is based on many factors, including your overall health and diagnosis. Your care team may change your dose of everolimus based on the level of everolimus in your blood.
- Take only everolimus tablets or everolimus tablets for oral suspension. Do not mix everolimus tablets and everolimus tablets for oral suspension together.
- Take everolimus 1 time each day, at about the same time.
- Take everolimus the same way each time, either with food or without food. Swallow everolimus whole with a glass of water. Do not crush or chew everolimus tablets.
- You should have blood tests before you start everolimus and as needed during your treatment. These will include tests to check your blood cell count, kidney and liver function, cholesterol, and blood sugar levels.

## Treatment Administration and Schedule Continued

- If you take everolimus to treat subependymal giant cell astrocytoma (SEGA) to treat certain types of seizures with tuberous sclerosis complex (TSC), you will also need to have blood tests regularly to measure how much medicine is in your blood. This will help your care team decide how much everolimus you need to take. Do not change your dose or stop taking everolimus unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking everolimus if you develop certain side effects.
- If you vomit or miss a dose of everolimus, you may take it if it is less than 6 hours after the time you normally take it. If it is more than 6 hours after you normally take your everolimus, skip the dose for that day. The next day, take everolimus at your usual time. Do not take 2 doses to make up for a missed dose. If you are not sure about what to do, call your care team.
- If you take too much everolimus, call your care team or go to the nearest hospital emergency room right away.

## For Patients Taking Everolimus Tablets for Oral Suspension

- Each dose of everolimus tablets for oral suspension must be prepared as a suspension before it is given.
- Take everolimus tablets for oral suspension as a suspension only. Everolimus tablets for oral suspension is prepared as a suspension of undissolved medicine that is mixed with water, and then it is taken by mouth.
- Only use water with everolimus tablets for oral suspension to prepare the suspension. Do not prepare the suspension with juice or any other liquids.
- The suspension must be given right away. If you do not give the dose within 60 minutes after it has been prepared, throw away the dose and prepare a new dose of everolimus tablets for oral suspension.
- Before starting to prepare the suspension, read the Instructions for Use that contains information on how to prepare and take or give a dose of everolimus.

## Storage and Handling of Everolimus

- Store everolimus at room temperature, between 68°F and 77°F (20°C and 25°C).
- Keep everolimus in the pack it comes in.
- Open the blister pack just before taking everolimus.
- Keep everolimus tablets or everolimus tablets for oral suspension dry and away from light.
- Do not use everolimus that is out of date or no longer needed.
- If someone else is giving you your medication, they should wear gloves or pour the pills directly from the bottle into the cap, a small cup, or your hand without touching them. They should wash their hands before and after handling the pills.
- Keep everolimus and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused everolimus.

## Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

**Supportive Care to Prevent and Treat Side Effects**

Description	Supportive Care Taken at Home
To help prevent mouth sores and irritation	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>

**Common Side Effects**

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Wash your hands often and bathe regularly.</li> <li>• Avoid crowded places and close contact with people who are sick.</li> <li>• Follow food safety and wound care advice from your care team.</li> <li>• Your care team may prescribe medicine to help your WBCs recover.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• Chills</li> <li>• New or worsening cough or sore throat</li> <li>• Painful urination or signs of a urinary infection</li> <li>• Feeling much more tired than usual</li> <li>• Red, swollen, warm, or painful areas on the skin (possible skin infection)</li> </ul>

<p>Low Platelet Count (Thrombocytopenia)</p>	<p>Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Blow your nose gently and avoid picking it.</li> <li>• Brush your teeth gently with a soft toothbrush and keep good oral hygiene.</li> <li>• Use an electric razor for shaving and a nail file instead of nail clippers.</li> <li>• Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen).</li> <li>• Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• A nosebleed lasting more than 5 minutes despite pressure</li> <li>• A cut that continues to bleed</li> <li>• Heavy gum bleeding when brushing or flossing</li> <li>• Sudden or severe headache</li> <li>• Blood in your urine or stool</li> <li>• Blood in your spit after coughing</li> </ul>
<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</p>	<p>Description: RBCs and Hgb carry oxygen to your body’s tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Aim for 7 to 8 hours of sleep each night.</li> <li>• Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired.</li> <li>• Balance activity and rest — stay as active as you can, but rest when needed.</li> <li>• Eat a balanced diet and follow any nutrition or supplement advice from your care team.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Dizziness or fainting</li> <li>• Fast or irregular heartbeats</li> <li>• Sudden or severe headache</li> </ul>
<p>High Cholesterol and Triglycerides Levels in Your Blood (Hyperlipidemia)</p>	<p>Description: Treatment can raise cholesterol and triglyceride levels in your blood. While cholesterol is needed by the body, high levels can increase the risk of heart disease. Triglycerides are blood fats and very high levels may raise the long-term risk of inflammation of your pancreas (pancreatitis) or heart problems.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Adopt a diet low in saturated and trans fats, increase fiber intake, and engage in regular physical activity.</li> <li>• Maintain a healthy weight.</li> <li>• Get regular cholesterol tests and inform the care team of any significant changes.</li> <li>• Do not smoke and limit alcohol consumption.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain</li> </ul>

<p>Mouth Sores or Irritation (Mucositis or Stomatitis)</p>	<p>Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Rinse your mouth after meals and at bedtime; rinse more often if sores develop.</li> <li>• Brush your teeth gently with a soft toothbrush or use a cotton swab after meals.</li> <li>• Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water.</li> <li>• Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth.</li> <li>• Avoid tobacco, alcohol, and alcohol-based mouthwash.</li> <li>• Your care team may prescribe medicines or mouth treatments to help with pain and healing.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Painful mouth sores or throat pain</li> <li>• Trouble eating or significant weight loss</li> </ul>
<p>Liver Problems</p>	<p>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Yellowing of your skin or the white part of your eyes (jaundice)</li> <li>• Severe nausea or vomiting</li> <li>• Pain on the right side of your stomach area (abdomen)</li> <li>• Dark, tea-colored urine</li> <li>• Bleeding or bruising more easily than normal</li> </ul>
<p>Changes in Electrolytes and Other Laboratory Results</p>	<p>Description: Treatment may cause low levels of phosphate in your blood and increased activated partial thromboplastin time (aPTT). aPTT is a blood test that shows how long it takes your blood to clot. If this level is higher than normal, you may bleed more easily. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• New or worsening muscle weakness, cramps, or bone pain</li> <li>• Trouble breathing or shortness of breath</li> <li>• Confusion, slurred speech, or severe dizziness</li> <li>• Severe fatigue or inability to perform daily activities</li> <li>• Nosebleed lasting over 5 minutes despite pressure</li> <li>• Cut that continues to bleed</li> <li>• Significant gum bleeding when flossing or brushing</li> <li>• Severe headaches</li> <li>• Blood in your urine or stool</li> <li>• Blood in your spit after a cough</li> </ul>

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Kidney Problems	<ul style="list-style-type: none"> <li>• Decrease in your amount of urine</li> <li>• Blood in your urine</li> <li>• Swelling of your ankles</li> <li>• Loss of appetite</li> </ul>
Lung Problems	<ul style="list-style-type: none"> <li>• Cough</li> <li>• Shortness of breath</li> <li>• Chest pain</li> </ul>
Allergic Reactions, Including Anaphylaxis	<p>Get emergency medical help right away if you develop any of the following signs or symptoms:</p> <ul style="list-style-type: none"> <li>• Swelling of your lips, mouth, tongue, or throat</li> <li>• A very fast heartbeat</li> <li>• Trouble breathing or swallowing</li> <li>• You feel dizzy or faint</li> <li>• Raised red areas on your skin (hives)</li> </ul>

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.  
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- **Treatment may affect your ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
  - If you are able to become pregnant:
    - Take a pregnancy test before starting treatment.
    - Use an effective method of birth control during treatment and for 8 weeks after your last dose of everolimus.
    - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 4 weeks after your last dose of everolimus.
- **Do NOT breastfeed** during treatment and for 2 weeks after your last dose of everolimus.

### Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **7 days** after each dose of **everolimus**:

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

### Additional Information

- **Tell your care team about all the medicines you take.**

This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.

- You should not receive a "live vaccine" or be around people who have recently received a "live vaccine" during your treatment with everolimus. If you are not sure about the type of immunization or vaccine, ask your care team. For children with TSC and SEGA or certain types of seizures, work with your care team to complete the recommended childhood series of vaccines before your child starts treatment with everolimus.
- There is a possible increased risk for a type of allergic reaction called angioedema in people who take an Angiotensin-Converting Enzyme (ACE) inhibitor medicine during treatment with everolimus. Talk with your care team before taking everolimus if you are not sure if you take an ACE inhibitor medicine.
- **You should not drink grapefruit juice or eat grapefruit during treatment with everolimus.** Grapefruit may increase the amount of everolimus in your blood.
- **Treatment can cause reactivation of skin reactions that can happen after radiation therapy (radiation recall).** Limit sunlight exposure during treatment. Use sunscreen and wear protective clothing when you will be exposed to sunlight during treatment.
- **Wound healing problems.** Wound healing problems have happened in some people who take everolimus. Tell your care team if you plan to have any surgery before or during treatment with everolimus.
  - You should stop taking everolimus at least 3 weeks before planned surgery.
  - Your care team should tell you when you may start taking everolimus again after surgery.
- **This Patient Education Sheet may not describe all possible side effects.**  
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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