



Everolimus (Afinitor®)

Pronounced: e-ver-OH-li-mus

Classification: mTOR Inhibitor

About Everolimus (Afinitor®)

Everolimus is a type of targeted therapy. This means it works by targeting something specific to the cancer cells, therefore decreasing side effects caused by unwanted damage to the healthy cells. Everolimus is a kinase inhibitor that inhibits mTor kinase, an enzyme required for cell growth and survival. By blocking this enzyme, the medication prevents cell division and, in turn, tumor growth. The medication can also interrupt angiogenesis, the development of blood vessels to supply the tumor with nutrients, which they need to grow.

How to Take Everolimus

Everolimus is taken by mouth, in pill form. The medication comes in 2.5mg, 5 mg, and 10 mg oral tablets. The dose will be based on the person's size and cancer type. The tablets should be swallowed whole with a glass of water, with or without food. Do not crush, break, or chew the tablets. Take your dose around the same time every day.

Afinitor® Disperz: This medication is available in a form that can be dissolved in a liquid. If you are prescribed this type of everolimus, your pharmacist should provide you with detailed instructions on how to make the suspension (liquid form) and take the dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

If you miss a dose and it has been less than 6 hours since your regular dose time, take it as soon as you remember. If it has been more than 6 hours, skip the dose. Do not take 2 doses at once to make up for a missed dose.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, rifampin, phenytoin, St. John's wort, fluconazole, ketoconazole, clarithromycin, voriconazole, ritonavir, and diltiazem, carbamazepine, phenobarbital, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store this medication at room temperature, in a dry place and away from light. Keep the medication in the original packaging. You should not use a pillbox for this medication. Keep out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced

by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Everolimus

There are a number of things you can do to manage the side effects of everolimus. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Mouth Ulcers (Mucositis/Stomatitis)

Certain cancer treatments can cause [sores or soreness in your mouth](#) and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing [regular mouth care](#) can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight-ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication can cause life threatening infections, with or without a decrease in white blood cell counts.

White blood cells (WBC) are important for fighting infection. While receiving treatment, your [WBC count can drop](#), putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4 °F or 38 °C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- [Washing hands](#), both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent [mouth care](#).
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the [red cell count is low](#), you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the [count is low](#) you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Nail and Skin Changes

This medication can affect your nails and skin. Patients may develop a rash. The rash may appear red, bumpy, dry and feel sore. You may also develop very dry skin, which may crack, be itchy or become flaky or scaly. Skin may also appear darker. Tips for managing your skin include:

- Use a thick, alcohol-free emollient lotion or cream on your skin at least twice a day, including right after bathing.
- Avoid sun exposure, as it can worsen the rash or cause a severe burn. Use a sunscreen with an SPF of 30 or higher and wear a hat and sunglasses to protect your head and face from the sun.
- Bathe/shower in cool or lukewarm (not hot) water and pat your skin dry.
- Use soaps, lotions and laundry detergents without alcohol, perfumes or dyes.
- Wear gloves to wash dishes or do housework or gardening.
- Drink plenty of water and try not to scratch or rub your skin.
- Notify your healthcare team if you develop a rash, as this can be a sign of a reaction.
- If you develop peeling or blistering of the skin, notify your healthcare team right away.

While receiving this medication, you may develop an inflammation of the skin around the nail bed/cuticle areas of toes or fingers, which is called paronychia. It can appear red, swollen or pus filled. Nails may develop "ridges" in them or fall off. You may also develop cuts or cracks that look like small paper cuts in the skin on your toes, fingers or knuckles. These side effects may appear several months after starting treatment, but can last for many months after treatment stops.

- Follow the same recommendations for your skin (above).
- Don't bite your nails or cuticles or cut the cuticles.
- Keep your fingernails and toenails clean and dry.
- You may use nail polish, but do not wear fake nails.
- Notify your doctor or nurse if any nails fall off or you develop any of these side effects or other skin abnormalities.

Fatigue

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage [nausea and vomiting](#). In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Diarrhea

Your oncology care team can recommend medications to relieve [diarrhea](#). Also, try eating [low-fiber](#), bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Edema

Everolimus can cause fluid retention (edema). Symptoms include swelling in the feet and hands, and rapid weight gain. Report any of these symptoms to your healthcare team immediately.

Decrease in Appetite or Taste Changes

[Nutrition](#) is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham, and onion can add flavor to vegetables.

Elevated Blood Sugar, Cholesterol, and Triglycerides

This medication can cause blood sugar, cholesterol, and triglyceride levels to be elevated. Your healthcare team will monitor for this using blood tests. Let your care team know if you have diabetes or high cholesterol or triglyceride levels before starting treatment.

Wound Healing

This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Be sure to inform the team performing the surgical procedure that you are taking everolimus. You should also inform your oncology team that a surgical procedure is planned. You will need to stop taking the medication 1 week prior to surgery. You should not restart the medication for 2 weeks after your surgery or until any surgical incision has adequately healed. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team.

Live Vaccines

You, or anyone you live with, should avoid having live or live-attenuated vaccines while receiving this medication. These include herpes zoster (Zostavax) for shingles prevention, oral polio, measles, nasal flu vaccine (FluMist®), rotavirus and yellow fever vaccines.

Less common, but important side effects can include:

- **Lung or Breathing Problems:** Everolimus can cause pneumonitis, an inflammation of the lung tissue that is not caused by infection. You should notify your healthcare team right away if you notice worsening cough, shortness of breath or difficulty breathing or wheezing. If your healthcare provider suspects pneumonitis, he or she may decide to lower your dose or treat your symptoms with a steroid medication.
- **Angioedema:** This medication can cause a rare allergic type reaction called angioedema when used with certain ACE inhibitor medications (for example enalapril, lisinopril and losartan). Contact your healthcare team or go to the emergency room immediately if you experience difficulty breathing, or swelling of the tongue, mouth or throat while taking everolimus.
- **Kidney Problems:** This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

- **Radiation Sensitization and Radiation Recall:** Patients treated with radiation before taking, during or after taking this medication can have skin and visceral organ side effects such as redness and inflammation. It is important to talk to your provider about your history or plan to have radiation therapy.

Sexual & Reproductive Concerns

This medication may affect your reproductive system, resulting in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and [vaginal dryness](#). In addition, the desire for sex may decrease during treatment.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary for women during treatment and for at least 8 weeks after treatment, even if your menstrual cycle stops or you believe you are not producing sperm. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with everolimus and for 4 weeks after the last dose. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team. You should not breastfeed while taking this medication and for 2 weeks after the last dose.

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