

ORAL CHEMOTHERAPY EDUCATION



EVEROLIMUS

Name of your medication

Generic name — everolimus (eh-veh-ROH-lih-mus)
Brand name — Afinitor® (a-FIN-i-tor)

Approved uses

Everolimus is used to treat the following:

- Hormone receptor–positive (HR+), human epidermal growth factor receptor-2 (HER-2)-negative breast cancer, in combination with the medication exemestane
- Pancreatic cancer (i.e., pancreatic neuroendocrine tumor [PNET])
- Neuroendocrine tumor (NET) of the stomach and intestine (gastrointestinal) or lung
- Kidney cancer called renal cell carcinoma or angiomyolipoma and tuberous sclerosis complex
- Brain tumor called subependymal giant cell astrocytoma (SEGA)

Dose and schedule

Taking everolimus as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of everolimus is 10 milligrams (10 mg) to be taken by mouth at a scheduled time once a day.
- Your dose is based on many factors, including your height and weight, overall health, and diagnosis.
- Everolimus can be taken with or without food. Choose one (with food or without food) and take at the same time each day.
- Everolimus should be taken with a full glass of water.
- Everolimus is available as regular tablets and tablets used to make a suspension (Afinitor® Disperz). The regular tablets should be taken whole and not crushed, cut, or dissolved. The tablets used to make a suspension should not be crushed or cut but can be dissolved in water. If you are unable to swallow everolimus, talk to your care provider or pharmacist for possible options.
- If you miss a dose of everolimus:
 - Only take the missed dose if it has been less than six hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Everolimus has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Grapefruit or grapefruit juice may interact with everolimus; avoid eating or drinking these during treatment with everolimus.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.
- Avoid live vaccines during treatment with everolimus.

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Storage and handling

Handle everolimus with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store everolimus at room temperature (68°F–77°F) in a dry location away from light.
- Keep everolimus out of reach of children and pets.
- Leave everolimus in the provided packaging until it is ready to be taken.
- Whenever possible, give everolimus to yourself and follow the steps below. If a family member, friend, or caregiver needs to give everolimus to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the everolimus from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is **not** recommended to be used with everolimus.
- If you have any unused everolimus, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of everolimus.
- If you are traveling, put your everolimus's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Everolimus

Below are common side effects that have been known to happen in about one third or more of patients taking everolimus are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

| Possible Side Effect | Management |
|---|--|
| <p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p> | <p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations |
| <p>Changes in electrolyte and other laboratory values</p> <ul style="list-style-type: none"> • High glucose levels • High prothrombin time levels • High cholesterol levels • High triglyceride levels • Low bicarbonate levels • Low phosphate levels • Low calcium levels • Low albumin levels | <p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine |
| <p>Changes in liver function</p> | <p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Unusual bleeding or bruising |

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| Possible Side Effect | Management |
|---|--|
| <p>Mouth irritation or sores</p> | <p>Practice good mouth care.</p> <ul style="list-style-type: none"> • Rinse your mouth frequently. • Brush your teeth with a soft toothbrush or cotton swab after meals. • Use a mild nonalcohol mouth rinse at least four times a day (after eating and at bedtime). For example, you can use a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. • If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p> |
| <p>Rash or itchy skin</p> | <ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. <p>If your rash or itching continues to worsen, contact your care provider.</p> |
| <p>Decreased platelet count and increased risk of bleeding</p> | <p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, bleeding, or burns. • Blow your nose gently and do not pick your nose. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than five minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, blood in your urine or stool, coughing up blood, or prolonged and uncontrollable bleeding. You may need to take a break or "hold" your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p> |

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| Possible Side Effect | Management |
|---|---|
| <p>Changes in kidney function</p> | <p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following:</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet |
| <p>Decreased white blood cells (WBCs) and increased risk for infection, including respiratory tract infections</p> | <p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Report symptoms of a respiratory infection like a cough sneezing, runny nose, fever, and scratchy or sore throat to your provider.</p> <p>Check with your care provider before taking any medicine for a fever or chills.</p> |
| <p>Diarrhea (loose and/or urgent bowel movements)</p> | <p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake related to some other health problem. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p> |

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| Possible Side Effect | Management |
|---|---|
| Fatigue | <p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> Stay as active as possible, but know it is okay to rest as needed, too. Try to do some activity every day. Plan your activities, and do them at a time of day when you feel a bit more energetic. Avoid operating heavy machinery if you feel too tired. |
| Fluid retention or swelling | <ul style="list-style-type: none"> Do not stand for long periods of time. Keep your legs elevated when sitting or lying down. Avoid eating salty foods, which can increase swelling. Avoid wearing tight-fitting clothing and shoes. Weigh yourself daily. <p>Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> Swelling in the hands, feet, or legs Shortness of breath Weight gain of five pounds or more in a week |
| Abdominal pain | <p>Abdominal pain or discomfort may occur. Report any serious pain or symptoms to your care provider immediately.</p> |
| Headache | <p>Ask your provider what you may use to ease headaches. Contact your care provider immediately if your headache:</p> <ul style="list-style-type: none"> Follows a head injury Is severe, especially if it starts suddenly Does not go away after three days Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness |
| Muscle or joint pain or weakness | <ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know that it is okay to rest as needed, too. Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider how you may ease this discomfort.</p> |

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National Community Oncology
Dispensing Association, Inc.
PASSION FOR PATIENTS



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| Possible Side Effect | Management |
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| Nausea or vomiting | <ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lay down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help.</p> |
| Cough or shortness of breath | <p>A cough that does not produce any mucous or congestion relief (dry cough) may occur while taking this medication. If you experience any breathing problems or shortness of breath, notify your care provider immediately. This may be a serious side effect of the medication.</p> |
| Decreased appetite or weight loss | <p>Talk to your provider if you notice a decrease in your weight while taking this medication.</p> <p>When you don't feel like eating, try the following:</p> <ul style="list-style-type: none"> • Eat frequent meals instead of three large meals each day. • Keep snacks nearby so you can eat when you feel hungry. • Drink liquid nutritional supplements. <p>Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.</p> |

Serious side effects of everolimus

- ❑ Everolimus can cause lung and breathing problems. Tell your healthcare provider right away if you have new or worsening cough, shortness of breath, chest pain, or difficulty breathing or wheezing.
- ❑ Severe allergic reactions are a rare but serious side effect of everolimus. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
- ❑ If you are also taking a type of medication called an Angiotensin Converting Enzyme (ACE) inhibitor you may be at higher risk of facial swelling. Inform your care provider immediately if you notice swelling in your face.
- ❑ If you need to have a surgical or dental procedure, tell your doctor that you are taking everolimus. everolimus may need to be stopped until your wound heals after some types of surgery.
- ❑ Geriatric patients have a higher risk of death while taking everolimus and should be monitored closely.
- ❑ Everolimus may interfere with the effectiveness of vaccinations. Recommended vaccinations may need to be completed prior to starting everolimus therapy.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Everolimus remains in your body for several days after it is taken, so some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take everolimus, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or everolimus with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking everolimus. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of eight weeks after the last dose of everolimus.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking everolimus and for two weeks after the last dose of everolimus.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on everolimus, and you are encouraged to ask your care provider.

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Obtaining medication

Talk with your care provider about how to obtain your everolimus.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.us.afinitor.com

Product prescribing information:

www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/afinitor.pdf

Product resources: www.us.afinitor.com/sega-tuberous-sclerosis

www.us.afinitor.com/angiomyolipoma-tsc

www.us.afinitor.com/progressive-nonfunctional-gi-neuroendocrine-tumor

www.us.afinitor.com/lung-neuroendocrine-tumors

www.us.afinitor.com/advanced-pancreatic-neuroendocrine-tumors

Updated – March 9, 2020

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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