

Everolimus (Afinitor, Afinitor Disperz)

About This Medicine

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

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Swelling of the hands, feet, or any other part of the body
- Infection
- Tiredness and weakness
- Fever
- Decreased appetite (decreased hunger)
- Headache
- Cough
- Respiratory tract infection
- Rash

Note: Each of the side effects above was reported in 30% or greater of patients treated with everolimus. 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

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Inflammation (swelling) of the lungs, which can be life-threatening. You may have a dry cough or trouble breathing.
- Risk of severe and life-threatening infections
- Risk of angioedema if you are also taking a type of medicine called an ACE inhibitor. Symptoms may be swelling of the face, feeling like your tongue or throat are swelling, and trouble breathing.

- Severe allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**
- Severe soreness of the mouth and throat
- Changes in your kidney function, which may cause kidney failure
- Slow wound healing
- Severe increase in your blood sugar, cholesterol, and triglyceride levels
- Worsening side effects from radiation treatments received prior to, during, or after everolimus treatment, which may be severe. Your skin may become red or irritated, you may have severe soreness of the mouth and throat and/or inflammation (swelling) of your lungs. Let your doctor know if you have received radiation in the past or plan to receive radiation therapy.

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

- Everolimus may cause slow wound healing. It should not be given within at least 1 week of planned surgery and for at least 2 weeks and until adequate wound healing following major surgery. If you must have planned/emergency surgery, or have an accident that results in a wound, tell the doctor that you are on everolimus.
- Talk to your doctor before receiving any vaccinations during your treatment. Some vaccinations are not recommended while receiving everolimus. You should also avoid contact with people who have received live vaccines.
- This medicine may reactivate the hepatitis B virus. Talk to your doctor if you have ever had or might have a hepatitis B infection.

How to Take Your Medicine

- Take the medicine consistently with or without food at the same time each day.
- Do not mix the tablet and the oral suspension together.
- **Tablet:** Swallow whole with a glass of water. Do not break or crush tablets and do not take any tablet that is broken or crushed.
- **Oral Suspension:** Prepare suspension with water only. You should wear gloves to prepare the suspension for another person. Talk to your doctor, nurse and/or pharmacist for proper preparation, dosing, and administration. The oral suspension should not be prepared by someone who is pregnant or planning to become pregnant because it may cause harm to an unborn baby. Throw away any suspension that is not taken within 60 minutes of preparation.
- **Missed dose:** If you miss a dose, and it is within 6 hours of the missed dose, take the missed dose, otherwise, skip the missed dose and go back to your normal schedule. Do not take 2 doses at the same time or extra doses.
- **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. 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.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or 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).
- 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 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.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- 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.
- 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.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of everolimus in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and 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 everolimus. 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.
- Avoid the use of St. John's Wort while taking everolimus as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call the Doctor

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

- Fever of 100.4° F (38° C) or higher
- Chills
- Feeling dizzy or lightheaded
- Headache that does not go away
- Wheezing and/or trouble breathing
- Coughing up yellow, green, or bloody mucus
- Pain in your chest
- Dry cough or a cough that is bothersome
- Signs of angioedema: swelling of the face, feeling like your tongue or throat are swelling, and trouble breathing
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Tiredness and/or weakness that interferes with your daily activities
- Easy bleeding or bruising
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy



- Pain in your abdomen that does not go away
- Decreased or very dark urine
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 8 weeks after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 weeks after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- In women, menstrual bleeding may become irregular or stop while you are getting this medicine. Do not assume that you cannot become pregnant if you do not have a menstrual period.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 weeks after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, 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 or egg banking.

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