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2. Everolimus

Everolimus

Generic name: everolimus**Brand names:** [Afinitor](#), [Afinitor Disperz](#), [Zortress](#)**Dosage form:** oral tablet, tablet for oral suspension**Drug classes:** [MTOR inhibitors](#), [Selective immunosuppressants](#)Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Jun 2, 2023.[Uses](#) [Warnings](#) [Before taking](#) [Dosage](#) [Side effects](#) [Interactions](#) [FAQ](#)

What is everolimus?

Everolimus (Afinitor, Afinitor Disperz, Zortress) belongs to a class of drugs called kinase inhibitors. It is used to prevent organ transplant rejection and treat certain benign (noncancerous) and cancerous tumors.

Different brandnames and tablet strengths of everolimus are used for different conditions:

- [Afinitor](#) (2.5 mg, 5 mg, 7.5 mg and 10 mg tablets), Afinitor Disperz (2 mg, 3 mg and 5 mg tablets for oral suspension) and generic versions of these are used to treat certain benign (noncancerous) and cancerous tumors.
- [Zortress](#) (0.25 mg, 0.5 mg, 0.75 mg and 1 mg tablets) and generic versions of it are used to prevent organ transplant rejection.

Everolimus is an inhibitor of a kinase called mammalian target of rapamycin (mTOR), which plays an important role in a pathway that regulates things such as how cells in your body multiply, form new blood vessels and use nutrients.

In people with tumors, everolimus works by reducing the blood flow to the tumor, which slows down the growth of tumors. Everolimus does this by binding to a protein called FKBP-12 and forming a complex, which blocks the activity of mTOR.

In people with a transplanted liver or kidney, everolimus acts as an immunosuppressant to prevent your body from attacking or rejecting the transplanted organ. Everolimus works by stopping a type of white blood cell called lymphocytes from activating and multiplying. These cells usually help our bodies fight off invading organisms, but after an organ transplant you don't want your immune system cells attacking or rejecting the new organ. Everolimus inhibits both antigenic and interleukin (IL-2 and IL-15) stimulation of lymphocytes.

Everolimus was approved by the US Food and Drug Administration (FDA) in 2009.

What is everolimus used for?

The Afinitor brand of everolimus is a prescription medicine used to treat:

- advanced hormone receptor-positive, HER2-negative [breast cancer](#), along with the medicine exemestane, in

postmenopausal women who have already received certain other medicines for their cancer.

- adults with a type of [pancreatic cancer](#) known as pancreatic neuroendocrine tumor (PNET), that has progressed and cannot be treated with surgery.
- adults with a type of cancer known as neuroendocrine tumor (NET) of the stomach and intestine (gastrointestinal), or lung that has progressed and cannot be treated with surgery.

It is not for use in people with carcinoid tumors that actively produce hormones.

- adults with advanced [kidney cancer](#) (renal cell carcinoma or RCC) when certain other medicines have not worked.
- people with the following types of tumors that are seen with a genetic condition called tuberous sclerosis complex (TSC):
 - adults with a kidney tumor called angiomyolipoma, when their kidney tumor does not require surgery right away.
 - adults and children 1 year of age and older with a brain tumor called subependymal giant cell astrocytoma (SEGA) when the tumor cannot be removed completely by surgery.

The Afinitor Disperz brand of everolimus is a prescription medicine used to treat:

- adults and children 1 year of age and older with a genetic condition called tuberous sclerosis complex (TSC) who have a brain tumor called subependymal giant cell astrocytoma (SEGA) when the tumor cannot be removed completely by surgery.
- adults and children 2 years of age and older with a genetic condition called tuberous sclerosis complex (TSC) who have certain types of seizures (epilepsy), as an added treatment to other antiepileptic medicines.

The Zortress brand of everolimus is a prescription medicine used to:

- prevent transplant rejection (antirejection medicine) in people who have received a [kidney transplant](#) or liver transplant.
- it is used with other medicines called cyclosporine, corticosteroids and certain other transplant medicines to prevent rejection of your transplanted kidney. It is used with other medicines called tacrolimus and corticosteroids to prevent rejection of your transplanted liver.

It is not known if everolimus:

- is safe and effective in children to treat:
 - hormone receptor-positive, HER-2 negative breast cancer
 - a type of cancer called neuroendocrine tumors (NET)
 - kidney cancer (renal cell carcinoma)
 - a kidney tumor called angiomyolipoma, that can happen in children with a genetic condition called tuberous sclerosis complex (TSC)
- is safe and effective in transplanted organs other than the kidney and liver.
- sold under the Zortress brand is safe and effective in children under 18 years of age

Important information

Important information you should know if you are taking everolimus to treat a tumor

This medication can cause serious side effects, including:

1. You may develop lung or breathing problems. In some people lung or breathing problems may be severe and can lead to death. Tell your healthcare provider right away if you have any of these symptoms:

- New or worsening cough
- Shortness of breath
- Chest pain
- Difficulty breathing or wheezing

2. You may be more likely to develop an infection, such as pneumonia, or a bacterial, fungal or viral infection. Viral infections may include active hepatitis B in people who have had hepatitis B in the past (reactivation). In some people (including adults and children) these infections may be severe and can lead to death. You may need to be treated as soon as possible.

Tell your healthcare provider right away if you have a temperature of 100.5°F or above, chills, or do not feel well.

Symptoms of hepatitis B or infection may include the following:

- Fever
- Chills
- Skin rash
- Joint pain and swelling
- Tiredness
- Loss of appetite
- Nausea
- Pale stools or dark urine
- Yellowing of the skin
- Pain in the upper right side of the stomach

3. Severe allergic reactions. Call your healthcare provider or get medical help right away if you get signs and symptoms of a severe allergic reaction, including: rash, itching, hives, flushing, trouble breathing or swallowing, chest pain or dizziness.

4. 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 healthcare provider before taking this medication if you are not sure if you take an ACE inhibitor medicine. Get medical help right away if you have trouble breathing or develop swelling of your tongue, mouth, or throat during treatment with this medications.

5. Mouth ulcers and sores. Mouth ulcers and sores are common during treatment with everolimus but can also be severe. When you start treatment with one of this medication, your healthcare provider may tell you to also start a prescription mouthwash to reduce the likelihood of getting mouth ulcers or sores and to reduce their severity. Follow your healthcare provider's instructions on how to use this prescription mouthwash. If you develop pain, discomfort, or open sores in your mouth, tell your healthcare provider. Your healthcare provider may tell you to restart this mouthwash or to use a special mouthwash or mouth gel that does not contain alcohol, peroxide, iodine, or thyme.

6. You may develop kidney failure. In some people this may be severe and can lead to death. Your healthcare provider should do tests to check your kidney function before and during your treatment.

If you have any of the serious side effects listed above, you may need to stop taking everolimus for a while or use a lower dose. Follow your healthcare provider's instructions.

Important information you should know if you are taking everolimus to prevent transplant rejection

This medication can cause serious side effects, including:

- Increased risk of getting certain cancers. People who take this medication have a higher chance of getting lymphoma and other cancers, especially skin cancer. Talk to your doctor about your risk for cancer.
- Increased risk of serious infections. This medication weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with this medication that may lead to death. People taking this medication have a higher chance of getting infections caused by viruses, bacteria, and fungi (yeast).
 - Call your doctor if you have symptoms of infection, including fever or chills.
- Blood clot in the blood vessels of your transplanted kidney. If this happens, it usually occurs within the first 30 days after your kidney transplant. Tell your doctor right away if you:
 - have pain in your groin, lower back, side or stomach (abdomen)
 - make less urine or you do not pass any urine
 - have blood in your urine or dark colored urine (tea-colored)
 - have fever, nausea, or vomiting
- Serious problems with your transplanted kidney (nephrotoxicity). You will need to start with a lower dose of cyclosporine when you take it with everolimus. Your doctor should do regular blood tests to check your levels of both everolimus and cyclosporine.
- Increased risk of death that can be related to infection, in people who have had a heart transplant. You should not take everolimus without talking to your doctor if you have had a heart transplant.

See the section below "What are the side effects of everolimus?" for information about other serious side effects.

Who should not take everolimus?

Do not take everolimus if you have had a severe allergic reaction to everolimus.

Do not take everolimus if you are allergic to any of the ingredients in it. See below for a complete list of ingredients.

Talk to your healthcare provider before taking this medicine if you are allergic to:

- a medicine that contains sirolimus
- a medicine that contains temsirolimus

Ask your healthcare provider if you do not know.

 [Everolimus pregnancy and breastfeeding warnings](#) (more detail)

What should I tell my doctor before taking everolimus?

Before taking everolimus, tell your healthcare provider about all of your medical conditions, including if you:

- Have or have had kidney problems
- Have or have had liver problems
- Have diabetes or high blood sugar
- Have high blood cholesterol or triglyceride levels (fat in your blood)
- Have any infections
- Previously had hepatitis B
- Have skin cancer or it runs in your family
- have Lapp lactase deficiency or glucose-galactose malabsorption. You should not take everolimus to prevent transplant organ rejection if you have this disorder.
- Are scheduled to receive any vaccinations. 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 healthcare provider. For children with TSC and SEGA or certain types of seizures, work with your healthcare provider to complete the recommended childhood series of vaccines before your child starts treatment with everolimus.
- Are planning to have surgery or if you have had a recent surgery. You should stop taking everolimus if you are being treated for a tumor at least 1 week before planned surgery. See “What are the side effects of everolimus?” below.
- Have received radiation therapy or are planning to receive radiation therapy in the future. See “What are the side effects of everolimus?” below.

How should I take everolimus?

- Your healthcare provider will prescribe the dose of everolimus that is right for you.
- Take everolimus exactly as your healthcare provider tells you to.
- Do not stop taking everolimus or change your dose unless your doctor tells you to.
- **If you are taking everolimus to treat a tumor:**
 - Your healthcare provider may change your dose of everolimus or tell you to temporarily interrupt dosing, if needed.
 - Take only the tablets or the tablets for oral suspension. Do not mix the two together.
 - Use scissors to open the blister pack.
 - Take everolimus 1 time each day at about the same time.
 - Take everolimus the same way each time, either with food or without food.
 - 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.
 - If you take everolimus to treat SEGA or to treat certain types of seizures with TSC, you will also need to have blood tests regularly to measure how much medicine is in your blood. This will help your healthcare provider

decide how much everolimus you need to take.

- Swallow everolimus tablets whole with a glass of water. Do not take any tablet that is broken or crushed.
- If your healthcare provider prescribes everolimus tablets for oral suspension, see the “Instructions for Use” that comes with your medicine for instructions on how to prepare and take your dose.
- Each dose of everolimus tablets for oral suspension must be prepared as a suspension before it is given.
- Everolimus tablets for oral suspension can cause harm to an unborn baby. When possible, the suspension should be prepared by an adult who is not pregnant or planning to become pregnant.
- Wear gloves to avoid possible contact with everolimus when preparing the suspensions of everolimus tablets for oral suspension for another person.

• If you are taking everolimus to prevent transplant rejection:

- Take everolimus at the same time as your dose of cyclosporine medicine.
- Do not stop taking or change your dose of cyclosporine or tacrolimus medicine unless your doctor tells you to.
- If your doctor changes your dose of cyclosporine, your dose of everolimus may change.
- Take everolimus 2 times a day about 12 hours apart.
- Swallow everolimus tablets whole with a glass of water. Do not crush or chew everolimus tablets.
- Take everolimus tablets with or without food. If you take everolimus tablets with food, always take everolimus tablets with food. If you take everolimus tablets without food, always take everolimus tablets without food.
- Your doctor will do regular blood tests to check your kidney function while you take everolimus. It is important that you get these tests done when your doctor tells you to. Blood tests will monitor how your kidneys are working and make sure you are getting the right dose of everolimus and other transplant medications they may be on (cyclosporine and tacrolimus).

 [Detailed Everolimus dosage information](#)

What happens if I miss a dose?

If you are taking everolimus to treat a tumor and you miss a dose, 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 healthcare provider.

What happens if I overdose?

If you are taking everolimus to treat a tumor and you take too much, contact your healthcare provider or go to the nearest hospital emergency room right away. Take the pack of everolimus with you.

If you are taking everolimus to prevent transplant rejection, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking everolimus?

- You should not drink grapefruit juice or eat grapefruit during your treatment with everolimus. It may make the amount of everolimus in your blood increase to a harmful level.
- Avoid receiving any live vaccines while taking everolimus. Some vaccines may not work as well while you are taking this medication.
- Avoid becoming pregnant. See the section Pregnancy and breastfeeding below.
- If you are taking everolimus to prevent transplant rejection, limit the amount of time you spend in the sunlight. Avoid using tanning beds or sunlamps. People who take everolimus have a higher risk of getting skin cancer. See the section “Important information” Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if you have fair skin or if you have a family history of skin cancer.

What are the side effects of everolimus?

If you are taking everolimus to treat a tumour:

Everolimus can cause serious side effects, including:

- See “Important information” above for more information.
- Risk of wound healing problems. Wounds may not heal properly during everolimus treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with everolimus.
 - You should stop taking everolimus at least 1 week before planned surgery.
 - Your healthcare provider should tell you when you may start taking everolimus again after surgery.
- Increased blood sugar and fat (cholesterol and triglyceride) levels in the blood. Your healthcare provider should do blood tests to check your fasting blood sugar, cholesterol, and triglyceride levels in the blood before you start and during treatment with everolimus.
- Decreased blood cell counts. Everolimus can cause you to have decreased red blood cells, white blood cells, and platelets. Your healthcare provider should do blood tests to check your blood cell counts before you start and during treatment with everolimus.
- Worsening side effects from radiation treatment, that can sometimes be severe. Tell your healthcare provider if you have had or are planning to receive radiation therapy.

The most common side effects of everolimus in people with advanced hormone receptor-positive, HER2-negative breast cancer, advanced neuroendocrine tumors of the pancreas, stomach and intestine (gastrointestinal) or lung, and advanced kidney cancer include:

- Infections
- Rash
- Feeling weak or tired
- Diarrhea
- Swelling of arms, hands, feet, ankles, face, or other parts of the body
- Stomach-area (abdominal) pain
- Nausea

- Fever
- Cough
- Headache
- Decreased appetite

The most common side effects of everolimus in people who have SEGA, renal angiomyolipoma, or certain types of seizures with TSC include respiratory tract infections.

Other side effects that may occur with everolimus:

- Absence of menstrual periods (menstruation). You may miss 1 or more menstrual periods. Tell your healthcare provider if this happens.
- Everolimus may affect fertility in females and may affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.
- Everolimus may affect fertility in males and may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

If you are taking everolimus to prevent transplant rejection:

Everolimus may cause serious side effects, including:

- See "Important information" above.
- swelling under your skin especially around your mouth, eyes and in your throat (angioedema). Your chance of having swelling under your skin is higher if you take everolimus along with certain other medicines. Tell your doctor right away or go to the nearest emergency room if you have any of these symptoms of angioedema:
- sudden swelling of your face, mouth, throat, tongue or hands
 - hives or welts
 - itchy or painful swollen skin
 - trouble breathing
- delayed wound healing. Everolimus can cause your incision to heal slowly or not heal well. Call your doctor right away if you have any of the following symptoms:
 - your incision is red, warm or painful
 - blood, fluid, or pus in your incision
 - your incision opens up
 - swelling of your incision
- lung or breathing problems. Tell your doctor right away if you have new or worsening cough, shortness of breath, difficulty breathing or wheezing. In some patients lung or breathing problems have been severe, and can even lead to death. Your doctor may need to stop everolimus or lower your dose.
- increased cholesterol and triglycerides (fat in your blood). If your cholesterol and triglyceride levels are high your doctor may want to lower them with diet, exercise and certain medicines.
- protein in your urine (proteinuria).

- change in kidney function. Everolimus may cause kidney problems when taken along with a standard dose of cyclosporine medicine instead of a lower dose.

Your doctor should do blood and urine tests to monitor your cholesterol, triglycerides and kidney function.

- viral infections. Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with everolimus include BK virus-associated nephropathy. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
- blood clotting problems.
- diabetes. Tell your doctor if you have frequent urination, increased thirst or hunger.
- infertility, male. Everolimus can affect fertility in males and may affect your ability to father a child. Talk with your doctor if this is a concern for you.
- infertility, female. Everolimus can affect fertility in females and may affect your ability to become pregnant. Talk to your doctor if this is a concern for you.

The most common side effects of everolimus in people who have had a kidney or liver transplant include:

These common side effects have been reported in both kidney and liver transplant patients:

- nausea
- swelling of the lower legs, ankles and feet
- high blood pressure

The most common side effects of everolimus in people who have had a kidney transplant include:

- constipation
- low red blood cell count (anemia)
- urinary tract infection
- increased fat in the blood (cholesterol and triglycerides)

The most common side effects of everolimus in people who have had a liver transplant include:

- diarrhea
- headache
- fever
- abdominal pain
- low white blood cells

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of everolimus. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Interactions

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Everolimus may affect the way other medicines work, and other medicines can affect how everolimus works. Taking everolimus with other medicines can cause serious side effects.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine. Especially tell your healthcare provider if you take:

- St. John's Wort (*Hypericum perforatum*)
- Medicine for:
 - Fungal infections
 - Bacterial infections
 - Tuberculosis
 - Seizures
 - HIV-AIDS
 - Heart conditions or high blood pressure
 - High cholesterol or triglycerides
- Medicines that weaken your immune system (your body's ability to fight infections and other problems) such as:
 - cyclosporine (Sandimmune, Gengraf, Neoral)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one of those taken for the conditions

listed above. If you are taking any medicines for the conditions listed above, your healthcare provider might need to prescribe a different medicine or your dose of everolimus may need to be changed. You should also tell your healthcare provider before you start taking any new medicine.

 [Everolimus drug interactions](#) (more detail)

Does everolimus interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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Add

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, can become pregnant, or have a partner who can become pregnant. Everolimus can cause harm to your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with everolimus.
- You should use effective birth control during treatment and for 8 weeks after your last dose of everolimus.
- Everolimus tablets for oral suspension can cause harm to an unborn baby. When possible, the suspension should be prepared by an adult who is not pregnant or planning to become pregnant.

Males with a female partner, you should use effective birth control during treatment and for 4 weeks after your last dose of everolimus.

Talk to your healthcare provider about birth control methods that may be right for you during this time. If you become pregnant or think you are pregnant, tell your healthcare provider right away.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if everolimus passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of everolimus.

Storage

- Store Afinitor and Afinitor Disperz branded everolimus tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store Zortress branded everolimus tablets between 59°F and 86°F (15°C and 30°C).
- Keep everolimus in the pack it comes in.
- Open the blister pack just before taking .
- Keep everolimus. dry and away from light.

- Do not use everolimus tablets to treat a tumor if they are out of date or no longer needed.

Keep everolimus and all medicines out of the reach of children.

What are the ingredients in everolimus?

Active ingredient: everolimus.

Inactive ingredients:

Afinitor tablets: anhydrous lactose, butylated hydroxytoluene, crospovidone, hypromellose, lactose monohydrate, and magnesium stearate.

Afinitor Disperz tablets: butylated hydroxytoluene, colloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, and microcrystalline cellulose.

Zortress tablets: butylated hydroxytoluene, magnesium stearate, lactose monohydrate, hypromellose, crospovidone and lactose anhydrous.

Generic versions of Afinitor, Afinitor Disperz and Zortress are available. Inactive ingredients in generic versions of these tablets may vary from those listed in the branded versions of everolimus listed above. Check the product label for the version of everolimus you take to find out all the ingredients in that particular version.

Everolimus is distributed under the brandname Afinitor, Afinitor Disperz and Zortress by Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. Other companies also manufacture generic versions of these tablets.

Frequently asked questions

- [How much does Afinitor cost per month?](#)
- [How long can you take Afinitor for?](#)
- [How long can you take everolimus?](#)
- [What is everolimus used for and how does it work?](#)
- [How does Afinitor work?](#)

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References

1. [National Library of Medicine Afinitor and Afinitor Disperz Product](#)
2. [National Library of Medicine Zortress Product Label](#)
3. [Food and Drug Administration \(FDA\) Everolimus Proprietary Name Review\(s\).](#)

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Patient resources

Other brands

[Afinitor](#), [Zortress](#), [Afinitor Disperz](#)

Professional resources

- [Everolimus monograph](#)
- [Everolimus Tablets \(FDA\)](#)

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[Afinitor](#), [Zortress](#), [Torpenz](#)

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- [Organ Transplant, Rejection Prophylaxis](#)
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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.


[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only


[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

5.6 / 10

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