

MEDICATION GUIDE

Everolimus (E ver OH li mus) Tablets

What is the most important information I should know about everolimus?

Everolimus can cause serious side effects, including:

- **Increased risk of getting certain cancers.** People who take everolimus 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.** Everolimus weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with everolimus that may lead to death. People taking everolimus 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 “What are the possible side effects of everolimus?” for information about other serious side effects.

What is everolimus?

Everolimus is a prescription medicine used to prevent transplant rejection (antirejection medicine) in people who have received a kidney transplant or liver transplant. Transplant rejection happens when the body's immune system perceives the new transplanted kidney as “foreign” and attacks it.

Everolimus is used with other medicines called cyclosporine, corticosteroids and certain other transplant medicines to prevent rejection of your transplanted kidney. Everolimus 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 transplanted organs other than the kidney and liver.

It is not known if everolimus is safe and effective in children under 18 years of age.

Do not take everolimus if you are allergic to:

- everolimus (Afinitor[®]) or any of the ingredients in everolimus tablets. See the end of this Medication Guide for a complete list of ingredients in everolimus tablets.
- sirolimus (Rapamune[®])

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

- have liver problems
- have skin cancer or it runs in your family

- have high cholesterol or triglycerides (fat in your blood)
- have Lapp lactase deficiency or glucose-galactose malabsorption. You should not take everolimus if you have this disorder.
- are pregnant or could become pregnant. Everolimus may harm your unborn baby. If you are able to become pregnant you should use effective birth control during treatment and for 8 weeks after your last dose of everolimus. Talk to your doctor 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. You should not become pregnant during treatment with everolimus.
- are breastfeeding or plan to breastfeed. It is not known if everolimus passes into your breast milk.

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

Especially tell your doctor if you take:

- antifungal medicine
- antibiotic medicine
- heart medicine
- high blood pressure medicine
- a medicine to lower cholesterol or triglycerides
- cyclosporine (Sandimmune, Gengraf, Neoral)
- tuberculosis (TB) medicine
- HIV medicine
- St. John's Wort
- seizure (anticonvulsant) medicine
- cannabidiol (Epidiolex)

How should I take everolimus?

- Take everolimus exactly as your doctor tells you to.
- **Do not** stop taking everolimus or change your dose unless your doctor tells you to.
- 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).
- If you take too much everolimus, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking everolimus?

- Avoid receiving any live vaccines while taking everolimus. Some vaccines may not work as well while you are taking everolimus.

- Do not eat grapefruit or drink grapefruit juice while you are taking everolimus. Grapefruit may increase your blood level of everolimus.
- 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 **“What is the most important information I should know about everolimus?”** 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.
- Avoid becoming pregnant. See the section **“What should I tell my doctor before taking everolimus?”**

What are possible side effects of everolimus?

Everolimus may cause serious side effects, including:

- See **“What is the most important information I should know about everolimus?”**
- **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

These are not all of the possible side effects of everolimus.

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

How should I store everolimus?

- Store everolimus tablets between 59°F and 86°F (15°C and 30°C).
- Keep everolimus out of the light.
- Keep everolimus tablets dry.

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

General information about the safe and effective use of everolimus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use everolimus for a condition for which it was not prescribed. Do not give everolimus to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about everolimus that is written for healthcare professionals.

What are the ingredients in everolimus?

Active ingredient: everolimus

Inactive ingredients: anhydrous lactose, butylated hydroxytoluene, crospovidone, hypromellose and magnesium stearate

Manufactured by:
NATCO PHARMA LIMITED
Kothur- 509228,
Telangana, India.

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berkeley Heights, NJ 07922

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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