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Everolimus

pronounced as (e" ver oh' li mus)

IMPORTANT WARNING:

Taking everolimus may decrease your ability to fight infection from bacteria, viruses, and fungi and increase the risk that you will get a serious or life-threatening infection. If you have had hepatitis B (a type of liver disease) in the past, your infection may become active and you may develop symptoms during your treatment with everolimus. Tell your doctor if you have or have ever had hepatitis B or if you have or think you may have any type of infection now. Tell your doctor and pharmacist if you are taking other medications that suppress the immune system such as azathioprine (Imuran), cyclosporine (Gengraf, Neoral, Sandimmune), dexamethasone (Decadron, Dexpak), methotrexate (Rheumatrex, Trexall), prednisolone (Orapred, Pediapred, Prelone), prednisone (Sterapred), sirolimus (Rapamune), and tacrolimus (Prograf). If you experience any of the following symptoms, call your doctor immediately: excessive tiredness; yellowing of the skin or eyes; loss of appetite; nausea; joint pain; dark urine; pale stools; pain in the upper right part of the stomach; rash; difficult, painful, or frequent urination; ear pain or drainage; sinus pain and pressure; or sore throat, cough, fever, chills, feeling unwell or other signs of infection.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to everolimus.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide [Zortress] or patient information leaflet [Afinitor, Afinitor Disperz]) when you begin treatment with everolimus and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking everolimus.

For patients who are taking everolimus to prevent transplant rejection:

You must take everolimus under the supervision of a doctor who is experienced in taking care of transplant patients and giving medications that suppress the immune system.

The risk that you will develop cancer, especially lymphoma (cancer of a part of the immune system) or skin cancer is increased during your treatment with everolimus. Tell your doctor if you or anyone in your family has or has ever had skin cancer or if you have fair skin. To reduce your risk of skin cancer, plan to avoid unnecessary or prolonged exposure to sunlight or ultraviolet light (tanning beds and sunlamps) and to wear protective clothing, sunglasses, and sunscreen during your treatment. If you experience any of the following symptoms, call your doctor immediately: a red, raised, or waxy area on the skin; new sores, bumps, or discoloration on the skin; sores that do not heal; lumps or masses anywhere in your body; skin changes; night sweats; swollen glands in the neck, armpits, or groin; trouble breathing; chest pain; or weakness or tiredness that does not go away.

Taking everolimus may increase the risk that you will develop certain very rare and serious infections, including infection with the BK virus, a serious virus that may damage the kidneys and cause a transplanted kidney to fail), and progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability). Call your doctor immediately if you experience any of the following symptoms of PML: weakness on one side of the body that worsens over time; clumsiness of the arms or legs; changes in your thinking, walking, balance, speech, eyesight, or strength that last several days; headaches; seizures; confusion; or personality changes.

Everolimus may cause a blood clot in the blood vessels of your transplanted kidney. This is most likely to happen within the first 30 days after your kidney transplant and may cause the transplant to be unsuccessful. If you experience any of the following symptoms, call your doctor immediately: pain in your groin, lower back, side, or stomach; decreased urination or no urination; blood in your urine; dark-colored urine; fever; nausea; or vomiting.

Taking everolimus in combination with cyclosporine could cause damage to your kidneys. In order to reduce this risk, your doctor will adjust the dose of cyclosporine and monitor the levels of the medications and how your kidneys are working. If you experience either of the following symptoms, call your doctor immediately: decreased urination or swelling of the arms, hands, feet, ankles, or lower legs.

In clinical studies, more people who took everolimus died during the first few months after receiving a heart transplant than people who did not take everolimus. If you have received a heart transplant, talk to your doctor about the risks of taking everolimus.

Why is this medication prescribed?

Everolimus (Afinitor) is used to treat advanced renal cell carcinoma (RCC; cancer that begins in the kidneys) that has already been treated unsuccessfully with other medications. Everolimus (Afinitor) is also used to treat a certain type of advanced breast cancer that has already been treated with at least one other medication. Everolimus (Afinitor) is also used to treat a certain type of cancer of the pancreas, stomach, intestines, or lungs that has spread or progressed and that cannot be treated with surgery. Everolimus (Afinitor) is also used to treat kidney tumors in people with tuberous sclerosis complex (TSC; a genetic condition that causes tumors to grow in many organs). Everolimus (Afinitor and Afinitor

Disperz) is also used to treat subependymal giant cell astrocytoma (SEGA; a type of brain tumor) in adults and children 1 year of age and older who have TSC. Everolimus (Afinitor Disperz) is also used along with other medications to treat certain types of seizures in adults and children 2 years of age and older who have TSC. Everolimus (Zortress) is used with other medications to prevent transplant rejection (attack of the transplanted organ by the immune system of the person who received the organ) in certain adults who have received kidney transplants. Everolimus is in a class of medications called kinase inhibitors. Everolimus treats cancer by stopping cancer cells from reproducing and by decreasing blood supply to the cancer cells. Everolimus prevents transplant rejection by decreasing the activity of the immune system.

How should this medicine be used?

Everolimus comes as a tablet to take by mouth and as a tablet to suspend in water and take by mouth. When everolimus is taken to treat kidney tumors, SEGA, or seizures in people who have TSC; RCC; or breast, pancreatic, stomach, intestine, or lung cancer, it is usually taken once a day. When everolimus is taken to prevent transplant rejection, it is usually taken twice a day (every 12 hours) at the same time as cyclosporine. Everolimus should either always be taken with food or always without food. Take everolimus at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take everolimus exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Everolimus tablets come in individual blister packs that can be opened with scissors. Do not open a blister pack until you are ready to swallow the tablet it contains.

You should take either everolimus tablets or everolimus tablets for oral suspension. Do not take a combination of both of these products.

Swallow the tablets whole with a full glass of water; do not split, chew, or crush them. Do not take tablets that have been crushed or broken. Tell your doctor or pharmacist if you are not able to swallow the tablets whole.

If you are taking the tablets for oral suspension (Afinitor Disperz), you must mix them with water before use. Do not swallow these tablets whole, and do not mix them with juice or any liquid other than water. Do not prepare the mixture more than 60 minutes before you plan to use it, and dispose of the mixture if it is not used after 60 minutes. Do not prepare the medication on a surface that you use to prepare or eat food. If you will be preparing the medication for someone else, you should wear gloves to prevent contact with the medication. If you are pregnant or plan to become pregnant, you should avoid preparing the medication for someone else, because contact with everolimus may harm your unborn baby.

You can mix the tablets for oral suspension in an oral syringe or in a small glass. To prepare the mixture in an oral syringe, remove the plunger from a 10-mL oral syringe and place the prescribed number of tablets in the barrel of the syringe without breaking or crushing the tablets. You can prepare up to 10 mg of everolimus in a syringe at one time, so if your dose is greater than 10 mg, you will need to prepare it in a second syringe. Replace the plunger in the syringe and draw about 5 mL of water and 4 mL of air into the syringe and place the syringe into a container with the tip pointing up. Wait 3 minutes to allow the tablets to go into suspension. then pick up the syringe and gently turn it up and down it five times. Place the syringe into the patient's mouth and push the plunger to administer the medication. After the patient

has swallowed the medication, refill the same syringe with 5 mL of water and 4 mL of air and swirl the syringe to rinse out any particles that are still in the syringe. Give this mixture to the patient to be sure that he or she receives all of the medication.

To prepare the mixture in a glass, place the prescribed number of tablets into a small drinking glass that holds no more than 100 mL (about 3 ounces) without crushing or breaking the tablets. You can prepare up to 10 mg of everolimus in a glass at one time, so if your dose is greater than 10 mg, you will need to prepare it in a second glass. Add 25 mL (about 1 ounce) of water to the glass. Wait 3 minutes and then gently stir the mixture with a spoon. Have the patient drink the entire mixture immediately. Add another 25 mL of water to the glass and stir with the same spoon to rinse out any particles that are still in the glass. Have the patient drink this mixture to be sure that he or she receives all of the medication.

Your doctor may adjust your dose of everolimus during your treatment depending on the results of your blood tests, your response to the medication, side effects you experience, and changes in other medications that you take with everolimus. If you are taking everolimus to treat SEGA or seizures, your doctor will adjust your dose not more often than once every 1 to 2 weeks, and if you are taking everolimus to prevent transplant rejection, your doctor will adjust your dose not more often than once every 4 to 5 days. Your doctor may stop your treatment for a time if you experience severe side effects. Talk to your doctor about how you are feeling during your treatment with everolimus.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking everolimus,

- tell your doctor and pharmacist if you are allergic to everolimus, sirolimus (Rapamune), temsirolimus (Torisel), any other medications, or any of the ingredients in everolimus tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin), captopril (Capoten), enalapril (Vasotec), fosinopril (Monopril), lisinopril (Prinivil, Zestril), moexipril (Univasc) perindopril (Aceon), quinapril (Accupril), ramipril (Altace), or trandolapril (Mavik); amprenavir (Agenerase), atazanavir (Reyataz), aprepitant (Emend), carbamazepine (Carbatrol, Epitol, Tegretol), clarithromycin (Biaxin, in Prevpac), digoxin (Digitek, Lanoxicaps, Lanoxin), diltiazem (Cardizem, Dilacor, Tiazac), efavirenz (in Atripla, Sustiva), erythromycin (E.E.S., E-Mycin, Erythrocin), fluconazole (Diflucan), fosamprenavir (Lexiva), indinavir (Crixivan), itraconazole (Sporanox), ketoconazole (Nizoral), nelfinavir (Viracept), nefazodone, nevirapine (Viramune), nicardipine (Cardene), phenobarbital (Luminal), phenytoin (Dilantin, Phenytek), rifabutin (Mycobutin), rifampin (Rifadin, in Rifamate, in Rifater), rifapentine (Priftin), ritonavir (Norvir, in Kaletra), saquinavir (Invirase), telithromycin (Ketek), verapamil (Calan, Covera, Isoptin, Verelan), and voriconazole (Vfend). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with everolimus, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.

- tell your doctor if you have or have ever had diabetes or high blood sugar; high levels of cholesterol or triglycerides in your blood; kidney or liver disease; or any condition that prevents you from digesting foods containing sugar, starch, or dairy products normally.
- tell your doctor if you are pregnant or plan to become pregnant. If you are a woman who is able to become pregnant, you must use effective birth control during your treatment and for 8 weeks after your final dose. If you are male with a female partner who could become pregnant, you must use effective birth control during your treatment and for 4 weeks after your final dose. Talk to your doctor about methods of birth control that will work for you. If you or your partner become pregnant while taking everolimus, call your doctor. Everolimus may harm the fetus. Tell your doctor if you are breastfeeding. Do not breastfeed during your treatment and for 2 weeks after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking everolimus.
- do not have any vaccinations without talking to your doctor. During your treatment with everolimus, you should avoid close contact with other people who have recently been vaccinated.
- talk to your child's doctor about vaccinations that your child may need to receive before beginning his or her treatment with everolimus.
- you should know that you may develop sores or swelling in your mouth during your treatment with everolimus, especially during the first 8 weeks of treatment. When you start treatment with everolimus, your doctor may prescribe a certain mouthwash to reduce the chance that you will get mouth ulcers or sores and to reduce their severity. Follow your doctor's instructions on how to use this mouthwash. Tell your doctor if you develop sores or feel pain in your mouth. You should not use any mouthwash without talking to your doctor or pharmacist because certain types of mouthwash that contain alcohol, peroxide, iodine, or thyme can worsen the sores and swelling.
- you should know that wounds or cuts, including the cut in the skin made during a kidney transplant may heal more slowly than normal or may not heal properly during your treatment with everolimus. Call your doctor right away if the cut in the skin from your kidney transplant or any other wound becomes warm, red, painful, or swollen; fills with blood, fluid, or pus; or begins to open.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

What should I do if I forget a dose?

If you remember the missed dose within 6 hours of the time you were scheduled to take it, take the missed dose right away. However, if more than 6 hours have passed since the scheduled time, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Everolimus may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- constipation
- change in ability to taste food

- weight loss
- dry mouth
- weakness
- headache
- difficulty falling asleep or staying asleep
- nosebleed
- dry skin
- acne
- problems with nails
- hair loss
- pain in the arms, legs, back or joints
- muscle cramps
- missed or irregular menstrual periods
- heavy menstrual bleeding
- difficulty getting or keeping an erection
- anxiety
- aggression or other changes in behavior

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- hives
- itching
- swelling of the hands, feet, arms, legs, eyes, face, mouth, lips, tongue, or throat
- hoarseness
- difficulty breathing or swallowing
- wheezing
- flushing
- chest pain
- extreme thirst or hunger
- unusual bleeding or bruising
- pale skin
- fast or irregular heartbeat
- dizziness
- seizures

Everolimus may decrease fertility in men and women. Talk to your doctor about the risks of taking everolimus.

Everolimus may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the blister pack it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light and excess heat and moisture (not in the bathroom). Keep the blister packs and tablets dry.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Afinitor[®]
- Afinitor Disperz[®]
- Zortress[®]

Other names

- RAD001

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