

PATIENT INFORMATION

EVEROLIMUS (E-ver-OH-li-mus) TABLETS

Read this Patient Information leaflet that comes with everolimus tablets before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

Everolimus tablets can cause serious side effects. These serious side effects include:

- You may develop lung or breathing problems.** In some people lung or breathing problems may be severe, and can even 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

- 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 even 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 inflammation
 - Tiredness
 - Loss of appetite
 - Nausea
 - Pale stools or dark urine
 - Yellowing of the skin
 - Pain in the upper right side of the stomach
- Severe allergic reactions.** Severe allergic reactions can happen in people who take everolimus tablets. 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.

- 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 tablets. Talk with your healthcare provider before taking everolimus tablets 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 everolimus tablets.

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

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

What are everolimus tablets?

Everolimus tablets are a prescription medicine used to treat:

- 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.

Who should not take everolimus tablets?

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

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

- sirolimus (Rapamune®)
- temsirolimus (Torisel®)

Ask your healthcare provider if you do not know.

What should I tell my healthcare provider before taking everolimus tablets?

Before taking everolimus tablets, 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 levels
- Have any infections
- Previously had hepatitis B
- 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 tablets. If you are not sure about the type of immunization or vaccine, ask your healthcare provider. For children with TSC and SEGA, work with your healthcare provider to complete the recommended childhood series of vaccines before your child starts treatment with everolimus tablets.
- Are pregnant, can become pregnant, or have a partner who can become pregnant. Everolimus tablets can cause harm to your unborn baby. If you are a female who is able to become pregnant you should use effective birth control during treatment and for 8 weeks after your last dose of everolimus tablets. If you are a male with a female partner, you should use effective birth control during treatment and for 4 weeks after your last dose of everolimus tablets. 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.
- 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 tablets.
- Are planning to have surgery or if you have had a recent surgery. You should stop taking everolimus at least 1 week before planned surgery. See "**What are the possible side effects of everolimus tablets?**"

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

Everolimus tablets may affect the way other medicines work, and other medicines can affect how everolimus tablets work. Taking everolimus tablets 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
- Medicines that weaken your immune system (your body's ability to fight infections and other problems)

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 tablets may need to be changed. You should also tell your healthcare provider before you start taking any new medicine.

How should I take everolimus tablets?

- Your healthcare provider will prescribe the dose of everolimus tablets that is right for you.
- Take everolimus tablets exactly as your healthcare provider tells you to.
- When you start treatment with everolimus tablets, your healthcare provider may also prescribe a 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.
- Your healthcare provider may change your dose of everolimus tablets or tell you to temporarily interrupt dosing, if needed.
- Take only everolimus tablets or everolimus tablets for oral suspension. Do not mix everolimus tablets and everolimus tablets for oral suspension together.
- See instructions at the end of this patient information sheet to open blister pack.

Everolimus Tablets:

- Swallow everolimus tablets whole with a glass of water. Do not take any tablet that is broken or crushed.
- Take everolimus tablets 1 time each day at about the same time.
- Take everolimus tablets the same way each time, either with food or without food.
- If you take too much everolimus tablets contact your healthcare provider or go to the nearest hospital emergency room right away. Take the pack of everolimus tablets with you.
- If you miss a dose of everolimus tablets, 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 tablets, skip the dose for that day. The next day, take everolimus tablets 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.
- You should have blood tests before you start everolimus tablets 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 tablets to treat SEGA, 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 tablets you need to take.

What should I avoid while taking everolimus tablets?

You should not drink grapefruit juice or eat grapefruit during your treatment with everolimus tablets. It may make the amount of everolimus tablets in your blood increase to a harmful level.

What are the possible side effects of everolimus tablets?

Everolimus tablets can cause serious side effects.

- See “What is the most important information I should know about everolimus tablets?” for more information.
- **Risk of wound healing problems.** Wounds may not heal properly during everolimus tablets treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with everolimus tablets.
 - You should stop taking everolimus tablets at least 1 week before planned surgery.
 - Your healthcare provider should tell you when you may start taking everolimus tablets 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 tablets.
- **Decreased blood cell counts.** Everolimus tablets 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 tablets.

The most common side effects of everolimus tablets in people with advanced kidney cancer include:

- Mouth ulcers. Everolimus tablets can cause mouth ulcers and sores. When you start treatment with everolimus tablets, 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 re-start this mouthwash or to use a special mouthwash or mouth gel that does not contain alcohol, peroxide, iodine, or thyme.
- 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 tablets in people who have SEGA or renal angiomyolipoma include:

- Mouth ulcers. Everolimus tablets can cause mouth ulcers and sores. When you start treatment with everolimus tablets, 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 re-start this mouthwash or to use a special mouthwash or mouth gel that does not contain alcohol, peroxide, iodine, or thyme.
- Respiratory tract infections.

Other side effects that may occur with everolimus tablets:

- Absence of menstrual periods (menstruation). You may miss 1 or more menstrual periods. Tell your healthcare provider if this happens.
- Everolimus tablets 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 tablets 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.

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 tablets. 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.

How should I store everolimus tablets?

- Store everolimus tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep everolimus tablets in the pack it comes in.
- Open the blister pack just before taking everolimus tablets.
- Keep everolimus tablets dry and away from light.
- Do not use everolimus tablets that are out of date or no longer needed.

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

General information about everolimus tablets

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

This leaflet summarizes the most important information about everolimus tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information written for healthcare professionals.

For more information call 1-800-367-3395 or go to www.bpirx.com.

What are the ingredients in everolimus tablets?

Active ingredient: everolimus.

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

How should I open everolimus tablets from child-resistant blister?

- Separate each unit of the blister individually through perforation and peel the lidding foil from “PEEL HERE” portion.
- Do not push everolimus tablets through the foil, may cause the tablet to break.



- Pull apart 1 of the blister units from the blister pack by tearing along the dotted lines (Perforations) until it is fully separated



- Peel the lidding foil from “PEEL HERE” portion.

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This Patient Information has been approved by the U.S. Food and Drug Administration.