AFINITOR® (everolimus) Tablets is a prescription medicine used to treat adults with a kidney tumor called angiomyolipoma, seen with a genetic condition called tuberous sclerosis complex (TSC), when their kidney tumor does not require surgery right away.

**INDICATION**

AFINITOR® Tablets is a prescription medicine used to treat adults with a kidney tumor called angiomyolipoma, seen with a genetic condition called tuberous sclerosis complex (TSC), when their kidney tumor does not require surgery right away.

**IMPORTANT SAFETY INFORMATION**

Patients should not take AFINITOR or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) if they are allergic to AFINITOR or AFINITOR DISPERZ or to any of its ingredients. Patients should tell their health care provider before taking AFINITOR or AFINITOR DISPERZ if they are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.

The brand names mentioned in this document are the property of their respective trademark owners.
IMPORTANT SAFETY INFORMATION
AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) can cause serious side effects that can even lead to death. If patients experience these side effects, they may need to stop taking AFINITOR or AFINITOR DISPERZ for a while or use a lower dose. Patients should follow their health care provider’s instructions.

Please see Important Safety Information throughout.
Click here for full Prescribing Information for AFINITOR, including Patient Information.
Find out how AFINITOR may help shrink TSC-related kidney tumors.

You or a loved one may have tuberous sclerosis complex (TSC), but by staying focused and working with your care team, you can learn about your condition, understand your treatment, and help ensure the best results possible.

AFINITOR® (everolimus) Tablets is approved to treat TSC-related kidney tumors in adult patients, when their kidney tumor does not require surgery right away. This brochure can help you learn more about AFINITOR, so that you know what to expect during treatment.

IMPORTANT SAFETY INFORMATION
Serious side effects include:

Lung or Breathing Problems: In some patients, lung or breathing problems may be severe and can even lead to death. Patients should tell their health care provider right away if they have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

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Click here for full Prescribing Information for AFINITOR, including Patient Information.
Renal angiomyolipomas are kidney tumors that can develop in people with TSC, which is a genetic disease. This means that certain genes inside the cells of a person with TSC do not function properly. In a series of actions, the genes send signals to growth factors, which stay switched on, causing benign (noncancerous) tumors to grow.

**UNDERSTANDING TSC**

**Without TSC**

- **TSC1** and **TSC2** genes make **PROTEINS (P)** to control **mTOR** and control **CELL** growth.

**With TSC**

- Defective **TSC1** and **TSC2** genes do not make **PROTEINS**, resulting in uncontrolled **CELL** growth. When cells grow out of control, tumors can develop, including in the kidneys.

**With TSC (treated with AFINITOR)**

- **AFINITOR®** (everolimus) controls **mTOR** and reduces tumor cell growth.

Please see Important Safety Information throughout. [Click here](#) for full Prescribing Information for AFINITOR, including Patient Information.
About 80% of people with TSC have kidney tumors

• These tumors are serious manifestations of TSC and often become more common (and larger) as you get older

• If the tumors continue to grow, they can damage normal, healthy kidney tissue, leading to the need for dialysis or kidney transplants

IMPORTANT SAFETY INFORMATION

Serious side effects include:

Infections: AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) may make patients more likely to develop an infection, such as pneumonia, or a bacterial, fungal, or viral infection. Viral infections may include reactivation of hepatitis B in people who have had hepatitis B in the past. In some people, these infections may be severe and can even lead to death. Patients may need to be treated as soon as possible. Patients should tell their health care provider right away if they 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, or pain in the upper right side of the stomach.

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.
In a 4-year study, AFINITOR® (everolimus) Tablets reduced the size of kidney tumors, starting at 6 months and continuing through 4 years. In the extension study, a total of 112 patients (79 patients received AFINITOR and 33 patients received placebo) participated in the study. The size of kidney tumors was measured at the start of the study, then at 12, 24, and 48 weeks—and every year from then on.

As early as 6 months, 42% of people had their tumor shrink to half its size.

IMPORTANT SAFETY INFORMATION
Serious side effects include:

Angioedema: Patients who take an angiotensin-converting enzyme (ACE) inhibitor medicine during treatment with AFINITOR or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) are at a possible increased risk for a type of allergic reaction called angioedema. Talk with your health care provider before taking AFINITOR or AFINITOR DISPERZ 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 AFINITOR or AFINITOR DISPERZ.

Please see Important Safety Information throughout.
Click here for full Prescribing Information for AFINITOR, including Patient Information.
At 4 years, 58% of patients had the size of their kidney tumors reduced by half.*

- Median length of treatment was about 4 years (range: 0.5 – 63.6 months)

*Patients also had no new kidney tumors ≥1 cm, no increase in kidney volume ≥20%, and no serious tumor-related bleeding.

**IMPORTANT SAFETY INFORMATION**

Serious side effects include:

**Kidney Failure:** Patients taking AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) may develop kidney failure. In some people, this may be severe and can even lead to death. Patients should have tests to check their kidney function before and during their treatment with AFINITOR or AFINITOR DISPERZ.

**Delayed Wound Healing:** AFINITOR or AFINITOR DISPERZ can cause incisions to heal slowly or not heal well. Call your health care provider right away if your incision is red, warm, or painful; if you have blood, fluid, or pus in your incision; if your incision opens up; or if your incision swells.

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.
At 4 years,

86% of people had no progression in their kidney tumors*

*No progression meant total kidney tumor volume did not increase more than 25% from the lowest volume measured, no tumors 1 cm or longer developed, neither kidney increased in volume by 20% or more from the lowest volume measured, and no serious kidney tumor–related bleeding was seen.

IMPORTANT SAFETY INFORMATION

Before taking AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension), tell your health care provider about all 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

(Continued on next page)

Please see Important Safety Information throughout.
Click here for full Prescribing Information for AFINITOR, including Patient Information.
In these patients, there was a noticeable improvement in 50% to 99% of their skin lesions. At 6 months, 26% of people had a visual improvement in their skin lesions.*

In these patients, there was a noticeable improvement in 50% to 99% of their skin lesions.

*Skin lesion response was determined for the 114 patients with TSC-related renal angiomyolipoma with ≥1 skin lesion at baseline. All skin lesion responses were partial responses, meaning there was visual improvement in 50% to 99% of all skin lesions and the improvement lasted for at least 8 weeks.

IMPORTANT SAFETY INFORMATION

Before taking AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension), tell your health care provider about all your medical conditions, including if you:

• 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 AFINITOR or AFINITOR DISPERZ. If you are not sure about the type of vaccine, ask your health care provider.
• Have other medical conditions.
• Are pregnant, or could become pregnant, or have a partner who could become pregnant. AFINITOR or AFINITOR DISPERZ can cause harm to your unborn baby. If you are a woman who is able to become pregnant, you should use effective birth control while using AFINITOR or AFINITOR DISPERZ and for 8 weeks after your last dose. If you are a male with a woman partner, you should use effective birth control during treatment and for 4 weeks after your last dose. Talk to your health care provider about birth control options while taking AFINITOR or AFINITOR DISPERZ.
• Are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose.
• Are about to have surgery, if you have had a recent surgery, or if you have an unhealed wound.

Please see Important Safety Information throughout.

Click here for full Prescribing Information for AFINITOR, including Patient Information.

Learn more at www.AFINITOR.com/angiomyolipoma
IMPORTANT SAFETY INFORMATION

Tell your health care provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) with certain other medicines can cause serious side effects. Keep a list of medicines you take and show it to your health care provider when you get a new medicine. Especially tell your health care provider if you take St John’s wort (Hypericum perforatum), medicines that weaken your immune system (your body’s ability to fight infections and other problems), or medicines for:

- Fungal infections
- Bacterial infections
- Tuberculosis

- Seizures
- HIV-AIDS
- Heart conditions or high blood pressure

If you are taking any medicines for the conditions listed above, your health care provider might need to prescribe a different medicine or your dose of AFINITOR or AFINITOR DISPERZ may need to be changed. Tell your health care provider before you start taking any new medicine.
IMPORTANT SAFETY INFORMATION

Common Side Effects: Common side effects include mouth ulcers. AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ™ (everolimus tablets for oral suspension) can cause mouth ulcers and sores. When you start treatment with AFINITOR or AFINITOR DISPERZ, your health care 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 health care provider’s instructions on how to use this prescription mouthwash. Tell your health care provider if you have pain, discomfort, or open sores in your mouth. Your health care provider may tell you to restart this mouthwash or to use a special mouthwash or gel that does not contain alcohol, hydrogen peroxide, iodine, or thyme.

Other common side effects include:

- Infections
- Feeling weak or tired
- Cough, shortness of breath
- Diarrhea and constipation
- Skin problems (such as rash, acne, dry skin, or itching)
- Nausea and vomiting
- Fever
- Loss of appetite, weight loss
- Swelling of arms, hands, feet, ankles, face, or other parts of the body
- Abnormal taste or dry mouth
- Inflammation of the lining of the digestive system
- Headache
- Nose bleeds
- Pain in arms and legs, mouth and throat, back or joints, or stomach area (abdomen)
- Low red blood cells, white blood cells, or platelets
- Increased blood cholesterol levels and certain other blood levels
- Decreased blood phosphate levels
- Increased blood sugar levels
- High blood pressure
- Difficulty sleeping
- Hair loss
- Muscle spasms
- Feeling dizzy
- Nail disorders
- Anxiety, aggression, and other abnormal behaviors

Other side effects that may occur with AFINITOR or AFINITOR DISPERZ:

- Absence of menstrual periods (menstruation). You may miss 1 or more menstrual periods. Tell your health care provider if this happens.
- AFINITOR or AFINITOR DISPERZ may affect fertility in females and males, and may affect your ability to become pregnant if you are female or your ability to father a child if you are male. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or does not go away.
These are not all the possible side effects of AFINITOR or AFINITOR DISPERZ. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.
WHAT IS THE MOST COMMON SIDE EFFECT?

The most common side effect of AFINITOR® (everolimus) Tablets in treating patients with TSC-related renal angiomyolipoma is mouth sores (also called ulcers), occurring in 78% of people taking AFINITOR. Tell your doctor if you have pain, discomfort, or open sores in your mouth. Before starting treatment, and during treatment, your doctor may offer some suggestions about proper oral care and foods to avoid. Below are general suggestions that you and your doctor may consider for the management of mouth sores.

**DO**

Eat soft foods such as milkshakes, smoothies, pudding, yogurt, mashed potatoes, or bananas.

Take good care of your mouth, and visit your dentist regularly.

Try to brush after every meal with a soft-bristled toothbrush and mild toothpaste.

**DON’T**

Don’t consume food and drinks that can irritate your mouth (such as citrus fruits and juices, tomatoes, spicy or salty foods, raw ginger, onions, and crunchy chips).

Don’t use a mouthwash that contains alcohol, hydrogen peroxide, iodine, or thyme because it may irritate your mouth.

Talk to your doctor right away if you have any questions or concerns. Your doctor or nurse may also provide you with a prescription treatment to help treat mouth sores.

Please see Important Safety Information throughout. [Click here](#) for full Prescribing Information for AFINITOR, including Patient Information.
TIPS ABOUT COMMON SIDE EFFECTS OF AFINITOR:

Some people experience many side effects when taking AFINITOR® (everolimus) Tablets, while others have few. It can be helpful to keep track of your experience by writing it down in a journal.

- AFINITOR works differently than treatments you may have had in the past, and it may cause side effects that you are not familiar with
- Tell your doctor if you have any side effect that bothers you or does not go away
- Your doctor or nurse may tell you to temporarily stop treatment until your symptoms improve, and then adjust your dose accordingly
- Your doctor may offer some suggestions about proper oral care and what foods to avoid

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Important Safety Information throughout. 
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TALKING WITH YOUR MEDICAL TEAM

Staying on treatment is important. This is why we recommend regular visits, screenings, and discussions with your medical team. Because TSC-related renal angiomyolipomas do not always have symptoms you can feel or see, these visits are important to any treatment plan.

Your doctor may adjust your dose to find the dosage strength of AFINITOR® (everolimus) Tablets that’s right for you. You should not change or adjust your dose by yourself. Always follow your doctor’s instructions, and contact your doctor or nurse if you are having any problems.

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

It may be helpful to keep track of your experience by writing it down in a journal.

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.
HOW TO TAKE AFINITOR

Take AFINITOR® (everolimus) Tablets exactly as your doctor tells you to. Your doctor may change your dose of AFINITOR or tell you to temporarily stop dosing, if needed.

TAKE AS FOLLOWS:

- Take AFINITOR one time each day at about the same time.
- Take AFINITOR the same way each time, either with food or without food.
- Use scissors to open the blister pack.
- Swallow AFINITOR tablets whole with a glass of water. Do not crush, chew, or take if broken or crushed.

If you take too much AFINITOR, contact your doctor or go to the nearest hospital emergency department right away. Take the pack of AFINITOR with you.

Please see Important Safety Information throughout.

Click here for full Prescribing Information for AFINITOR, including Patient Information.

Learn more at www.AFINITOR.com/angiomyolipoma
AVOID MISSING A DOSE

- If you miss a dose of AFINITOR® (everolimus) Tablets, you may still take it up to 6 hours after the time you normally take it. If it is more than 6 hours after you normally take AFINITOR, skip the dose for that day. The next day, take AFINITOR at your usual time.
- Do not take 2 doses to make up for the one that you missed.
- If you are not sure about what to do, call your health care provider.

OTHER IMPORTANT THINGS YOU SHOULD KNOW

- Don’t drink grapefruit juice or eat grapefruit during your treatment with AFINITOR. It may make the amount of AFINITOR in your blood increase to a harmful level.
- Avoid the use of live vaccinations and contact with individuals who have received live vaccinations. If you are not sure about the type of vaccine, ask your health care provider.

You should have blood tests before you start AFINITOR and throughout your treatment. These will include tests to check your blood cell count, liver function, kidney function, cholesterol, and blood sugar levels.
Learn more at www.AFINITOR.com/angiomyolipoma
AfiniTRAC®: The Support Program for Patients Taking AFINITOR® (everolimus)

AfiniTRAC is a support program for patients taking AFINITOR. AfiniTRAC Care Champions can provide you with 1-to-1 educational support throughout your treatment journey. Each Care Champion is a registered nurse with experience in areas such as oncology, nephrology, and pediatrics, as well as an understanding of TSC. Each patient is assigned to just one Care Champion; your Care Champion will call you regularly to ask how treatment is going and whether you have any questions.

**HOW YOUR CARE CHAMPION CAN HELP**

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<thead>
<tr>
<th>Your Care Champion nurse can support you in several ways</th>
<th>Information about financial assistance that may be available</th>
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</thead>
<tbody>
<tr>
<td>Help locating pharmacies covered by your plan</td>
<td>Help understanding insurance and Medicare coverage</td>
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<td></td>
<td>Personal phone calls that fit into your schedule</td>
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<td></td>
<td>Education about your medicine</td>
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<td>Help creating a customized dosing and mealtime routine</td>
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<td>Translation services in over 160 languages</td>
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Additional day-to-day patient support resources can provide information on a range of independent support organizations that offer services to complement your medical care, from transportation and meals to home cleaning.

Please see Important Safety Information throughout. [Click here](#) for full Prescribing Information for AFINITOR, including Patient Information.
When you register for AfiniTRAC, you will be matched with one of our Care Champion nurses who will provide you with ongoing, personalized support.

HOW CAN AfiniTRAC HELP?

I recently helped one patient who had started AFINITOR® (everolimus). Within the first month of therapy, she had moved, changed doctors, and acquired a new insurance policy. I was able to help her throughout the entire process to ensure that she didn’t miss any doses.

— Robin, AfiniTRAC Care Champion with 20 years’ nursing experience

HOW DO I ENROLL IN THE AfiniTRAC PROGRAM?

AfiniTRAC: 1-to-1 personalized support in just 3 steps

1) Ask your doctor for an AfiniTRAC enrollment form
2) Fill out the form and sign it (both you and your doctor need to do this)
3) Fax to 1-877-705-2282

For assistance, call 1-888-923-4648 or visit www.AFINITOR.com

AfiniTRAC does not replace patients’ regular interactions with their health care teams.

Please see Important Safety Information throughout.

Click here for full Prescribing Information for AFINITOR, including Patient Information.

Learn more at www.AFINITOR.com/angiomyolipoma
ADDITIONAL PATIENT RESOURCES

As a member of AfiniTRAC®, there are several resources available to you, including:

**FREE TRIAL PROGRAM**—Eligible patients can receive a free 7-day supply of AFINITOR® (everolimus) until coverage reviews are complete (if eligible; limitations apply).

**AFINITOR CO-PAY CARD**—You may be eligible for immediate co-pay savings on your next prescription.

- With the AFINITOR Co-pay Card, commercially insured patients pay $0 per month
- Novartis will pay the remaining co-pay for AFINITOR, up to $15,000 per calendar year
- Limitations apply. See program terms and conditions. This offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice

**FINANCIAL ASSISTANCE**—There are other ways we can help to make treatment with AFINITOR as affordable as possible. Visit www.AFINITOR.com for more information.

Please see Important Safety Information throughout. [Click here](#) for full Prescribing Information for AFINITOR, including Patient Information.
STAY IN TOUCH
You are often the best advocate for your own care. We encourage you to stay in close contact with your doctor. We also recommend that you keep learning about your condition and your treatment through the online resources and support programs we offer.
For more information, call 1-888-4AFINITOR (1-888-423-4648) or visit www.AFINITOR.com