AFINITOR® (everolimus) 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. It is not known if AFINITOR and AFINITOR DISPERZ are safe and effective in children to treat kidney tumors called angiomyolipoma, that can happen in children with TSC.

Please see Important Safety Information throughout.

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

The brands listed are the trademarks or registered trademarks of their respective owners and are not trademarks or registered trademarks of Novartis.
IMPORTANT SAFETY INFORMATION

AFINITOR or AFINITOR DISPERZ 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-associated 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-associated 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**

Please be aware of the following:

**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 health care provider right away if you have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

Please see Important Safety Information throughout. **Click here** for full Prescribing Information for AFINITOR, including Patient Information.
KIDNEY TUMORS AND TSC

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 THE CAUSE OF TSC

Without TSC

\[ TSC1 \quad \text{P} \quad mTOR \quad TSC2 \]

\[ TSC1 \quad TSC2 \]

\[ \text{TSC1 and TSC2 genes make PROTEINS (P) to control } mTOR \text{ and control CELL growth.} \]

\[ mTOR, \text{mammalian target of rapamycin.} \]

With TSC

\[ TSC1 \quad mTOR \quad TSC2 \]

\[ \times \]

\[ \text{Defective TSC1 and TSC2 genes do not make PROTEINS, resulting in uncontrolled CELL growth. When cells grow out of control, tumors can develop, including in the kidneys.} \]

With TSC (treated with AFINITOR)

\[ TSC1 \quad mTOR \quad TSC2 \]

\[ \text{AFINITOR® (everolimus) controls mTOR.} \]
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

Please be aware of the following:

You may be 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 (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. You should tell your health care 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, 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.
AFINITOR SHRINKS TSC-ASSOCIATED KIDNEY TUMORS AND MAY PREVENT NEW ONES FROM FORMING

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 participated in the study (79 patients received AFINITOR and 33 patients received placebo). 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

Please be aware of the following:

Severe Allergic Reactions. Severe allergic reactions can happen in people who take AFINITOR or AFINITOR DISPERZ. Call your health care 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.

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
Please be aware of the following:
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 AFINITOR or AFINITOR DISPERZ. 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.

You 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.

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

Learn more at www.us.AFINITOR.com/angiomyolipoma-tsc
At 4 years, 
86% of people had no progression in their kidney tumors* 

*No progression meant total kidney tumor volume did not increase 25% or more 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 or AFINITOR DISPERZ, 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
- 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 immunization or vaccine received, ask your health care provider. For children with TSC and SEGA, or certain types of seizures, work with your health care provider to complete the recommended childhood series of vaccines before your child starts treatment with AFINITOR or AFINITOR DISPERZ

Please see Important Safety Information throughout. 
Click here for full Prescribing Information for AFINITOR, including Patient Information.
AFINITOR PROVIDES IMPROVEMENTS IN TSC-ASSOCIATED SKIN CONDITIONS

At 6 months,
26% of people had a visual improvement in their skin conditions associated with TSC*

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

*Skin lesion response was determined for the 114 patients with TSC-associated 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 or AFINITOR DISPERZ, tell your health care provider about all your medical conditions, including if you:

• 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.
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 or AFINITOR DISPERZ 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

Ask your health care 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 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.

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

Not actual patients.
IMPORTANT SAFETY INFORMATION

Possible Side Effects of AFINITOR or AFINITOR DISPERZ:

AFINITOR and AFINITOR DISPERZ can cause serious side effects.

- **Delayed wound healing.** AFINITOR and AFINITOR DISPERZ can cause incisions to heal slowly or not heal well. Call your health care provider 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; and/or swelling of your incision.

- **Increased blood sugar and fat (cholesterol and triglyceride) levels in the blood.** Your health care provider should do blood tests to check your fasting blood sugar, cholesterol, and triglyceride levels in your blood before you start and during treatment with AFINITOR or AFINITOR DISPERZ.

- **Decreased blood cell counts.** AFINITOR and AFINITOR DISPERZ can cause you to have decreased red blood cells, white blood cells, and platelets. Your health care provider should do blood tests to check your blood cell counts before you start and during treatment with AFINITOR or AFINITOR DISPERZ.

The most common side effects of AFINITOR and AFINITOR DISPERZ in people who have SEGA, renal angiomyolipoma, or certain types of seizure with TSC:

- **Mouth ulcers:** AFINITOR or AFINITOR DISPERZ 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.

- **Respiratory tract infection**

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

- Absence of menstrual periods (menstruation). Women may miss 1 or more menstrual periods. Tell your health care provider if this happens.

- Fertility may be affected in women and may affect the ability to become pregnant. Talk to your health care provider if this is a concern for you.

- Fertility may be affected in men and may affect the ability to father a child. 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 people with TSC-associated renal angiomyolipomas is mouth sores (also called ulcers). Your doctor may refer to this as stomatitis. Before starting treatment, and during treatment, your doctor may offer suggestions for oral care and what foods to avoid. Below are tips that you and your doctor may consider to manage mouth sores.

If you have a young child, some of these tips might not be appropriate; ask your doctor for guidance.

**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.
- Floss regularly.
- Rinse your mouth several times a day with a mixture of table salt and water.
- Check with a doctor, nurse, or pharmacist before using a store-bought mouthwash.

**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.
- Don’t drink hot liquids.
- Don’t eat foods that you are allergic to, and keep in mind any dietary restrictions you may have.

Talk to your doctor right away if you have any questions or concerns. Your doctor or nurse may also provide you with a prescription for alcohol-free dexamethasone oral solution 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. Click here for full Prescribing Information for AFINITOR, including Patient Information.
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-associated 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.

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

Call your doctor for medical advice about side effects. You may also report side effects to the FDA at 1-800-FDA-1088.
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](https://www.us.AFINITOR.com/angiomyolipoma-tsc) for full Prescribing Information for AFINITOR, including Patient Information.
How to Take AFINITOR (continued)

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.
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

- Personal phone calls that fit into your schedule
- Education about your medicine
- Help creating a customized dosing and mealtime routine
- Translation services in more than 160 languages
- Information about financial assistance that may be available
- Help locating pharmacies covered by your plan
- Help understanding insurance and Medicare coverage
- Your Care Champion nurse can support you in several ways

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.

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 CAN AfiniTRAC HELP?

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
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.

To find out if you are eligible, call 1-877-577-7756, or visit www.CoPay.NovartisOncology.com

Universal Co-pay Card
Save on your out-of-pocket costs

To find out if you are eligible to save on your next prescription, call 1-877-577-7756 or visit us at www.CoPay.NovartisOncology.com

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.

Please see Important Safety Information throughout. Click here for full Prescribing Information for AFINITOR, including Patient Information.
For more information, call 1-888-4AFINITOR (1-888-423-4648)

or visit www.us.AFINITOR.com/angiomyolipoma-tsc

Please see Important Safety Information throughout.

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