

BEYOND YOUR TSC, THERE'S YOU.

www.us.AFINITOR.com/tsc-seizures

INDICATION

AFINITOR DISPERZ® (everolimus tablets for oral suspension) is a prescription medicine used to treat adults and children 2 years of age and older with a genetic condition called tuberous sclerosis complex (TSC) who have certain types of seizures (epilepsy), as an added treatment to other antiepileptic medicines.

IMPORTANT SAFETY INFORMATION

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



Please see Important Safety Information throughout.

<u>Click here</u> for full Prescribing Information for
AFINITOR DISPERZ, including Patient Information.









Alee's Journey With TSC-Associated Seizures

When Alee was born, she seemed healthy in every way. As the third child to Mindee and Rafe, Alee was a happy baby and soon fell into the normal routines of a bustling, busy Texas family. But that all changed when she was 5 months old.

Something began happening that frightened Mindee. When Alee fell asleep, she would startle and jump. And then shake. At first it only happened occasionally, but soon it became routine. Each time Alee fell asleep, she would shake

Mindee knew something wasn't right, but no doctors had an answer. She began sleeping next to Alee with her hand on her tiny baby's chest, so she would be aware of when it happened. Neither was getting any sleep, and Mindee was desperate for answers.

Then one night shortly before her first birthday, Alee had her first major seizure. She began gasping for breath—a terrifying, agonizing noise Mindee will never forget. As Mindee performed CPR on her tiny daughter, Rafe called 911. The ride to the hospital, with their 2 other young children in the back seat, felt like a nightmare.

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Please see Important Safety Information throughout.



ALEE'S JOURNEY WITH TSC-ASSOCIATED SEIZURES





Once there, Mindee and Rafe learned that Alee was having a major seizure that was very difficult to control. She needed to be transported to another hospital that was more equipped to handle her needs. As their tiny baby, now sedated and intubated, was placed in a medevac helicopter, the young parents could only stare in horror and sob.

During that next week, after many tests and consultations, Mindee heard the words she'll never forget: "Your daughter has tuberous sclerosis complex."

Alee had many partial-onset seizures every day in the weeks that followed. "She basically ate, slept, and seized," Mindee said. "We were in the hospital 1 to 2 days out of every week."

"In the beginning, when she was first diagnosed, I did feel very defeated. I cried a lot. I actually think I cried to the point where I did not have any tears left. I was pretty numb to everything that was going on in the world," Mindee said.

At this point, Alee had been on several antiepileptic drugs (AEDs), but her seizures were not well controlled. Then Mindee learned of a center that specialized in caring for patients with TSC and got an appointment.

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IMPORTANT SAFETY INFORMATION

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 DISPERZ for a while or use a lower dose. Patients should follow their health care provider's instructions.

Please see Important Safety Information throughout.



ALEE'S JOURNEY WITH TSC-ASSOCIATED SEIZURES







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<u>Click here</u> for full Prescribing Information for AFINITOR DISPERZ, including Patient Information.

Once there, the physician placed Alee on a medication that achieved some success by reducing the frequency of her seizures. Yet even with this progress, Alee's life was very difficult. Her family never knew when a seizure would come. She continued to have several more major seizures in those years, resulting in trips to the emergency department.

"Alee was still having quite a few seizures. Every day, every week, lots in a month. It was our normal. Our kids didn't know any different," Mindee said.

However, things began to change when Alee was 5 years old. That's when her doctor suggested that she enroll in a clinical trial for AFINITOR DISPERZ® (everolimus tablets for oral suspension), which was being studied in people who had failed on 2 or more AEDs.

As Mindee recalls: "When we started AFINITOR DISPERZ, Alee was having numerous seizures every day. After a few months, we could tell that they had decreased. And that was exciting. But then after about 8 or 9 months, her seizures decreased even more."

Alee had mouth sores when taking AFINITOR DISPERZ, which is the most common side effect. They went away when Alee's doctor prescribed a medicine for her to use as a mouthwash.

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ALEE'S JOURNEY WITH TSC-ASSOCIATED SEIZURES





By the end of the clinical trial's first year, Alee had seen progress. And now, she continues on treatment with AFINITOR DISPERZ® (everolimus tablets for oral suspension).

Mindee and Alee keep up with various doctors' appointments and stay on track with medication.

"I think it's just a choice you make every day," she said. "You have to decide that you're not going to let tuberous sclerosis run your life. We just have to make it through each day as it comes."



"When we started AFINITOR DISPERZ,
Alee was having numerous seizures
every day. After a few months, we could
tell that they had decreased.
And that was exciting. But then after
about 8 or 9 months, her seizures
decreased even more."
—Alee's mother, Mindee



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.





Please see Important Safety Information throughout.





TSC SEIZURES

AFINITOR DISPERZ

Find out how AFINITOR DISPERZ® (everolimus tablets for oral suspension) may help certain types of TSC-associated seizures, as an added treatment to other antiepileptic medicines.

SIDE EFFECTS OF AFINITOR DISPERZ

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.

HOW TO TAKE AFINITOR DISPERZ

PATIENT SUPPORT

Please see Important Safety Information throughout.





STAYING INFORMED

You or your loved one may have TSC. You also have the ability to be engaged and proactive about reaching your treatment goals. By staying focused and working with your care team, you can learn about the condition, understand the treatment, and ensure the best care possible.

AFINITOR DISPERZ® (everolimus tablets for oral suspension), in combination with other seizure medicines, is approved to treat TSC-associated seizures that are partial onset, meaning they affect one side of the brain. This brochure can help you learn more about AFINITOR DISPERZ and help you understand what to expect during treatment.

Embrace your role in finding the right care.

IMPORTANT SAFETY INFORMATION

Please be aware of the following:

Severe allergic reactions. Severe allergic reactions can happen in people who take 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.

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 DISPERZ. Talk with your health care provider before taking 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 DISPERZ.









Please see Important Safety Information throughout.





TSC AND SEIZURES

If you or your loved one has TSC and seizures, you are not alone. That's because seizures are the most common brain-related symptom of TSC.

Most people with TSC start having seizures as babies or toddlers. But about 12% of people with TSC who did not have seizures in their childhood experience their first one as adults.

People with TSC can have almost any type of seizure. Most people with TSC have a type of seizure called partial onset, which affects only a part of the brain. No matter which kind of seizure you or your family member has, it is very important to manage the condition with your neurologist. AFINITOR DISPERZ® (everolimus tablets for oral suspension) is approved to treat adults and children 2 years of age and older who have certain types of TSC-associated seizures (epilepsy), as an added treatment to other antiepileptic medicines.

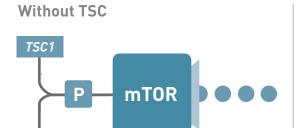


Approximately 85% of people with TSC have seizures



TSC AND SEIZURES (continued)

UNDERSTANDING THE CAUSE OF TSC



TSC1 and **TSC2** genes make **PROTEINS** to control **mTOR** and control **CELL** growth.

TSC2

mTOR, mammalian target of rapamycin.



Defective **TSC1** and **TSC2** do not make **PROTEINS**, resulting in uncontrolled **CELL** growth. When cells grow out of control, seizures can develop in the brain.

With TSC [treated with AFINITOR DISPERZ® (everolimus tablets for oral suspension)]



AFINITOR DISPERZ controls mTOR.

IMPORTANT SAFETY INFORMATION

Please be aware of the following:

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 DISPERZ.

Please see Important Safety Information throughout.



AFINITOR DISPERZ: A MEDICINE FOR CERTAIN TYPES OF TSC SEIZURES





AFINITOR DISPERZ® (everolimus tablets for oral suspension) is a prescription medicine used to treat adults and children 2 years of age and older with a genetic condition called tuberous sclerosis complex (TSC) who have certain types of seizures (epilepsy), as an added treatment to other antiepileptic medicines.



Please see Important Safety Information throughout.



AFINITOR DISPERZ: A MEDICINE FOR CERTAIN TYPES OF TSC SEIZURES (continued)



IMPORTANT SAFETY INFORMATION

Before taking 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
- 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 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 DISPERZ
- Are pregnant, or could become pregnant, or have a partner who could become pregnant.
 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 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 DISPERZ



WHEN ADDED TO PATIENTS' CURRENT SEIZURE MEDICINES,

AFINITOR DISPERZ HELPS PATIENTS HAVE FEWER SEIZURES

EXIST-3 Study



In a clinical study called EXIST-3, AFINITOR DISPERZ® (everolimus tablets for oral suspension) was evaluated to determine if it was effective and safe when added to a patient's current seizure medicine.

The study showed that when AFINITOR DISPERZ was taken along with other seizure medicines, it helped to reduce how often patients had seizures over 12 weeks.

The study had 3 groups of patients that received a treatment: placebo (sugar pill), high-dose AFINITOR DISPERZ, and low-dose AFINITOR DISPERZ.

After 12 weeks, 40% of patients in the high-dose AFINITOR DISPERZ group had fewer seizures than before treatment with AFINITOR DISPERZ. About 29% of patients in the low-dose AFINITOR DISPERZ group had fewer seizures, as did about 15% of patients in the placebo group.

PERCENTAGE OF PATIENTS WITH FEWER SEIZURES





High-dose **AFINITOR DISPERZ** group

(130 patients)



(117 patients)



Placebo group

(119 patients)

IMPORTANT SAFETY INFORMATION

Before taking AFINITOR DISPERZ, tell your health care provider about all your medical conditions, including if you:

- Are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose
- Are planning to have surgery or if you have had a recent surgery. You should stop taking AFINITOR DISPERZ at least 1 week before planned surgery

Please see Important Safety Information throughout.



AFINITOR DISPERZ HELPS PATIENTS HAVE FEWER SEIZURES (continued)

EXIST-3 Study



The study also measured how many patients had fewer seizures each week in the placebo and AFINITOR DISPERZ® (everolimus tablets for oral suspension) groups.

AVERAGE NUMBER OF SEIZURES EACH WEEK (MEDIAN)

	Placebo group (119 patients)	AFINITOR DISPERZ low-dose group (117 patients)	AFINITOR DISPERZ high-dose group (130 patients)
At start of study	10.5	8.6	9.5
During the study	8.5	6.8	4.9

RESULTS FOR THE PATIENTS IN THE 2 AFINITOR DISPERZ GROUPS WERE SIMILAR, REGARDLESS OF THESE 6 CHARACTERISTICS:

1 Age	4 Types of seizures
2 Gender	How often they had seizures at the start of the study
3 Race and ethnicity	The number of antiepileptic drugs they were taking





SAFETY INFORMATION FOR AFINITOR DISPERZ

IMPORTANT SAFETY INFORMATION

AFINITOR DISPERZ® (everolimus tablets for oral suspension) 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 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
- 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
- Severe allergic reactions. Severe allergic reactions can happen in people who take 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
- 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 DISPERZ. Talk with your health care provider before taking 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 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 DISPERZ

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





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 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

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 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 DISPERZ. It may make the amount of AFINITOR DISPERZ in your blood increase to a harmful level







IMPORTANT SAFETY INFORMATION

Possible Side Effects of AFINITOR DISPERZ® (everolimus tablets for oral suspension):

AFINITOR DISPERZ can cause serious side effects.

- **Risk of wound healing problems.** Wounds may not heal properly during treatment with AFINITOR DISPERZ. Tell your health care provider if you plan to have any surgery before starting or during treatment with AFINITOR DISPERZ. You should stop taking AFINITOR DISPERZ at least 1 week before planned surgery. Your health care provider should tell you when you may start taking AFINITOR DISPERZ again after surgery
- Increased blood sugar and fat (cholesterol and triglyceride) levels in 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 DISPERZ
- **Decreased blood cell counts.** 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 DISPERZ

The most common side effects of AFINITOR DISPERZ:

- Mouth ulcers: AFINITOR DISPERZ can cause mouth ulcers and sores. When you start treatment with 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





IMPORTANT SAFETY INFORMATION

Other side effects that may occur with AFINITOR DISPERZ® (everolimus tablets for oral suspension):

- 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 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.

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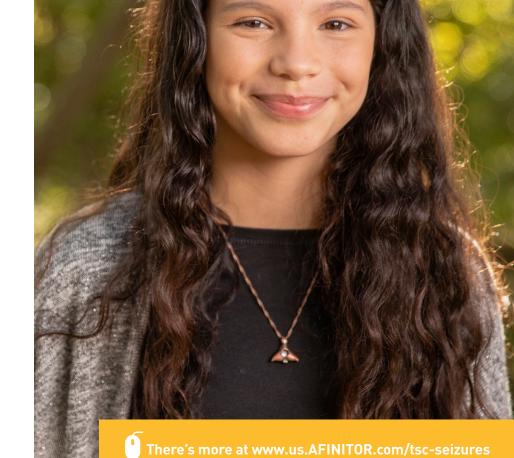




MANAGING SIDE EFFECTS

The most common side effect of AFINITOR DISPERZ® (everolimus tablets for oral suspension) in people with TSC-associated seizures 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. On the following page, there are tips that you and your doctor may consider to manage mouth sores. Ask your doctor which of these suggestions are appropriate for young children.

Talk to your doctor right away if you have any questions or concerns. If you have a young child, some of these tips might not be appropriate; ask your doctor for guidance. 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.



MANAGING SIDE EFFECTS (continued)

TIPS FOR MANAGING 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.



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.

Please see Important Safety Information throughout.





TIPS ABOUT COMMON SIDE EFFECTS OF AFINITOR DISPERZ:

With AFINITOR DISPERZ® (everolimus tablets for oral suspension), you may have side effects. That's why it is important to have frequent conversations with your doctor. You can make a management plan in case of side effects

Some people experience many side effects, while others have few. It can be helpful to keep track of your experience by writing it down in a journal.

- AFINITOR DISPERZ 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

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.





TALKING WITH YOUR MEDICAL TEAM

We understand that being able to stay on treatment is important to you. This is why we recommend regular visits, screenings, and discussions with your medical team.

Your doctor may adjust your dose to find the strength of AFINITOR DISPERZ® (everolimus tablets for oral suspension) 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.







HOW TO TAKE AFINITOR DISPERZ

The recommended starting dose is 5 mg/m² once every day, but your doctor will prescribe the dose of AFINITOR DISPERZ® (everolimus tablets for oral suspension) that is right for you or your loved one. AFINITOR DISPERZ does not replace the other seizure medicines you or your loved one is taking. Instead, it should be added to your medicine routine.

Take AFINITOR DISPERZ exactly as your doctor tells you to. Your doctor may change your dose or tell you to temporarily stop taking medicine, if needed.

TAKE AS FOLLOWS:



Take AFINITOR DISPERZ one time each day at about the same time.



Take AFINITOR DISPERZ the same way each time, either with food or without food.

FOLLOW THE INSTRUCTIONS FOR USE



If your doctor prescribes AFINITOR DISPERZ for you, see the "Instructions for Use" that come with your medicine for instructions on how to prepare and take your dose.



HOW TO TAKE AFINITOR DISPERZ (continued)

PREPARE THE DOSE WITH CARE



Each dose of AFINITOR DISPERZ® (everolimus tablets for oral suspension) must be prepared as a **suspension** (a mixture of the medicine + a liquid) before it is given. Prepare the suspension in water only.



Use scissors to open the blister pack.



AFINITOR DISPERZ can cause harm to an unborn baby. When possible, the suspension should be prepared by an adult who is not pregnant or planning to become pregnant.



Anyone who prepares suspensions of AFINITOR DISPERZ for another person should wear gloves to avoid possible contact with the medicine.

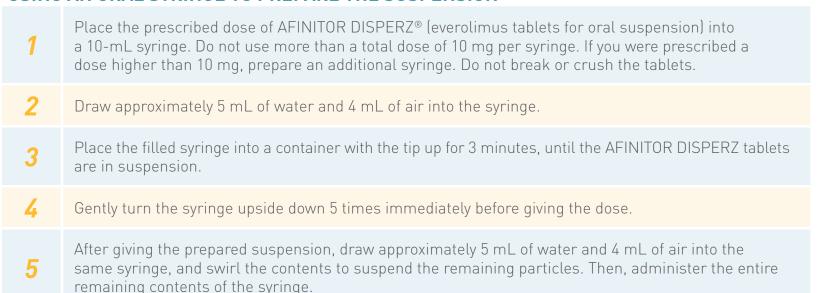
If you take too much AFINITOR DISPERZ, contact your doctor or go to the nearest hospital emergency department right away.

Take the pack of AFINITOR DISPERZ with you.



USE AN ORAL SYRINGE OR A SMALL GLASS

USING AN ORAL SYRINGE TO PREPARE THE SUSPENSION



You should have blood tests before you start AFINITOR DISPERZ and throughout your treatment. These will include tests to check your blood cell count, liver function, kidney function, cholesterol, and blood sugar levels.





USE AN ORAL SYRINGE OR A SMALL GLASS (continued)

USING A SMALL DRINKING GLASS

- Place the prescribed dose of AFINITOR DISPERZ® (everolimus tablets for oral suspension) into a small drinking glass containing approximately 25 mL of water (the glass should be no larger than 100 mL [about half a cup]). Do not use more than a total dose of 10 mg of AFINITOR DISPERZ per glass. If a dose higher than 10 mg was prescribed, prepare an additional glass. Do not break or crush the tablets.
- 2 Let the glass sit for 3 minutes to allow the suspension to occur.
- 3 Stir the contents gently with a spoon right before drinking.
- After drinking the prepared suspension, add 25 mL of water to the glass and stir with the same spoon to suspend the remaining particles. You should then drink the entire contents of the glass.

AVOID MISSING A DOSE

- If you miss a dose of AFINITOR DISPERZ, 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 your AFINITOR DISPERZ, skip the dose for that day. The next day, take AFINITOR DISPERZ 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 doctor or nurse

OTHER IMPORTANT THINGS YOU SHOULD KNOW



Don't drink grapefruit juice or eat grapefruit during your treatment with AFINITOR DISPERZ. It may make the amount of AFINITOR DISPERZ 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 doctor or nurse.





for oral suspension)

AFINITOR DISPERZ HAS THE PATIENT SUPPORT YOU NEED



The support program for patients taking AFINITOR or AFINITOR DISPERZ

Getting access to medications can sometimes be difficult or confusing. Novartis Pharmaceuticals Corporation is committed to helping you get the medicines you need. AfiniTRAC® offers tools and support designed specifically to help make that process easier.

What Is AfiniTRAC?

AfiniTRAC is a support program for eligible patients taking AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension).

The program provides 1-to-1 telephone support directly to patients through AfiniTRAC Care Champions.

AfiniTRAC Care Champions provide comprehensive educational support, including help with a treatment routine and reminders to patients to take medication as prescribed.

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.



The information obtained through the AfiniTRAC program is not intended to replace the advice and guidance of your health care team.

Please see Important Safety Information throughout.

<u>Click here</u> for full Prescribing Information for AFINITOR DISPERZ, including Patient Information.

Help locating pharmacies covered by your plan Help creating a customized dosing and mealtime routine Your Care Champion can help Your Care Champion can support you in several ways Help understanding insurance and Medicare coverage Help creating a customized dosing and mealtime routine Translation services in more than 160 languages

AFINITOR DISPERZ HAS THE PATIENT SUPPORT YOU NEED (continued)



AfiniTRAC® Care Champions

When you register for AfiniTRAC, you will be matched with one of our Care Champions who will provide you with support and education throughout your treatment journey with AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension).



How Can AfiniTRAC Help?

I recently helped one patient who had started AFINITOR. Within the first month of therapy, she moved, changed doctors, and acquired a new insurance policy. I was able to help the patient throughout the entire process without her missing any doses.*

-Robin, AfiniTRAC Care Champion

* This does not represent every patient outcome.



i Shevtsov/Shutters

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 AFINITOR.com

Please see Important Safety Information throughout.





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 DISPERZ® (everolimus tablets for oral suspension) until coverage reviews are complete (if eligible; limitations apply).



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

- Eligible patients with private insurance may pay \$0 per month
- Novartis will pay the remaining co-pay, up to \$15,000 per calendar year, per product*

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit Copay.NovartisOncology.com or call 1-877-577-7756.

To find out if you are eligible for the Universal Co-pay Program, call **1-877-577-7756** or visit **Copay.NovartisOncology.com**.

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

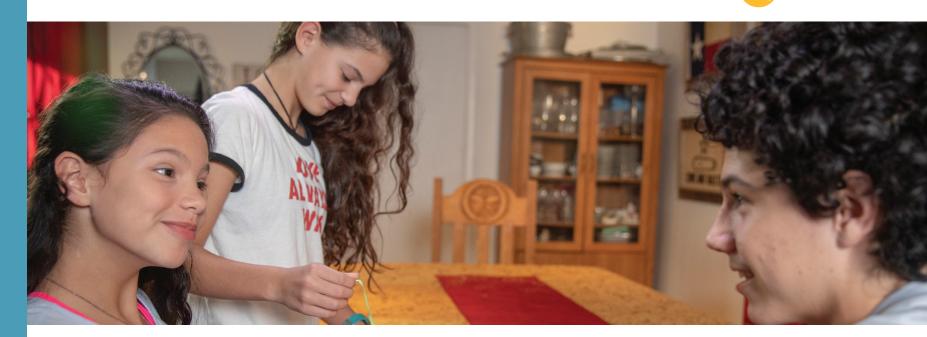




ADDITIONAL PATIENT RESOURCES (continued)

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 you keep learning about your condition and your treatment through the online resources and support programs we offer.



Visit www.us.AFINITOR.com/tsc-seizures to learn more and download helpful materials

www.us.AFINITOR.com/tsc-seizures has free materials to help you learn more about TSC seizures and AFINITOR DISPERZ® (everolimus tablets for oral suspension).

You can print these materials so you have this useful information close at hand. Remember to bring them with you to your doctor appointments to help your discussions.

BEYOND YOUR TSC WITH SEIZURES, THERE'S YOU.



