Getting started with AFINITOR

TAKING AFINITOR

AFINITOR® (everolimus) Tablets is a prescription medicine that is taken orally once a day. Take AFINITOR exactly as prescribed. Your health care provider may change your dose or temporarily interrupt dosing if needed. You will be regularly monitored to keep track of treatment progress and side effects.

You should have blood tests before you start AFINITOR 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.

Tell your health care provider about all medications and herbal supplements (e.g., St John’s Wort) you are taking, or if you start or stop any new medications/supplements while taking AFINITOR.

Take AFINITOR once a day at about the same time, consistently with food or without food.

If you take too much AFINITOR contact your health care provider or go to the nearest hospital emergency room right away. Take the pack of AFINITOR with you.

Use scissors to open the blister pack.

If you miss a dose of AFINITOR, 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 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 a missed dose. If you are not sure what to do, call your health care provider.

Swallow AFINITOR tablets whole with a glass of water. Do not take any tablet that is crushed, chewed, or broken.

AFINITOR should be kept in its original packaging at room temperature, away from light and moisture, until you are ready to take it.

Do not consume grapefruit during treatment. It may make the amount of AFINITOR in your blood increase to a harmful level.

IMPORTANT SAFETY INFORMATION

Do not take AFINITOR if you have had a severe allergic reaction to everolimus. AFINITOR can cause serious side effects, including lung or breathing problems, infections, and kidney failure, which can lead to death.

Please see following page for additional Important Safety Information and click here for full Prescribing Information, including Patient Information.
**BEING PROACTIVE**

Be sure to contact your doctor or nurse immediately if you experience shortness of breath, new or worsening cough or chest pain, or any early signs of mouth ulcers and sores. AFINITOR can cause lung or breathing problems, which can be serious. Fatal reactions have occurred.

Mouth ulcers and sores are the most common side effect of AFINITOR. They can appear as early as within the first 2 weeks of treatment or at any time during treatment. When you start treatment with AFINITOR, you may be prescribed a 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.

**Early signs of mouth ulcers and sores:**

- Sores or redness
- Feelings of tenderness, swelling, tingling, pain, or burning
- Changes in taste
- Difficulty eating spicy foods
- Difficulty eating, drinking, or swallowing

**Things to 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
- Rinse your mouth several times a day with a saltwater mixture
- If you’re flossing with dental floss, continue with your daily flossing routine. If you have not been flossing daily, do not start, because your mouth may become more sensitive
- Check with a doctor, nurse, or pharmacist before using a store-bought mouthwash

**Things to Avoid:**

- Foods and drinks that can irritate your mouth (such as citrus fruits and juices, tomatoes, spicy or salty foods, raw ginger, onions, and crunchy chips)
- Mouthwash that contains alcohol, hydrogen peroxide, iodine, or thyme, because it may irritate your mouth
- Drinking hot liquids or beverages
- Eating foods that you are allergic to. Also, keep in mind any dietary restrictions you may have

To learn about financial assistance and support resources that may be available, call 1-800-282-7630 or visit www.AFINITOR.com.

**IMPORTANT SAFETY INFORMATION**

Patients who take an angiotensin-converting enzyme (ACE) inhibitor medicine during treatment with AFINITOR are at a possible increased risk for a type of allergic reaction called angioedema.

AFINITOR can cause incisions to heal slowly or not heal well.

Please see following page for additional Important Safety Information and click here for full Prescribing Information, including Patient Information.
**ONCOLOGY INDICATIONS**

**Advanced Breast Cancer**
AFINITOR® (everolimus) Tablets is a prescription medicine used to treat advanced hormone receptor-positive, HER2-negative breast cancer, along with the medicine exemestane, in postmenopausal women who have already received certain other medicines for their cancer.

**Advanced Kidney Cancer**
AFINITOR is a prescription medicine used to treat adults with advanced kidney cancer (renal cell carcinoma or RCC) when certain other medicines have not worked.

**Advanced Pancreatic Neuroendocrine Tumor**
AFINITOR is a prescription medicine used to treat adults with a type of pancreatic cancer known as pancreatic neuroendocrine tumor (PNET) that has progressed and cannot be treated with surgery. AFINITOR is not for use in people with carcinoid tumors that actively produce hormones.

**Advanced GI/Lung NET**
AFINITOR is a prescription medicine used to treat adults with a type of cancer known as neuroendocrine tumor (NET) of the stomach and intestine (gastrointestinal) or lung that has progressed and cannot be treated with surgery. AFINITOR is not for use in people with carcinoid tumors that actively produce hormones.

**IMPORTANT SAFETY INFORMATION**

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

AFINITOR can cause serious side effects, some of which can be severe and can even lead to death. Your health care team may have ways to help manage side effects that do occur. It’s important to talk with your doctor or nurse about side effects you experience and the best ways to manage them. 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.

**Infections:** AFINITOR 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. 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, have 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. 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.

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

**Kidney Failure:** Patients taking AFINITOR may develop kidney failure. Patients should have tests to check their kidney function before and during their treatment with AFINITOR.

**Delayed Wound Healing:** AFINITOR 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.

**Increased Blood Sugar and Fat (cholesterol and triglycerides) 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.

**Decreased Blood Cell Counts:** AFINITOR 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.

Before taking AFINITOR, 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. If you are not sure about the type of vaccine, ask your health care provider.  

Please see following page for additional Important Safety Information and click here for full Prescribing Information, including Patient Information.
IMPORTANT SAFETY INFORMATION (CONTINUED)

• Are pregnant, could become pregnant, or have a partner who could become pregnant. AFINITOR® [everolimus] Tablets 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 and for 8 weeks after your last dose. Talk to your health care provider about birth control options while taking AFINITOR.

• 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.

Tell your health care provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using AFINITOR 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 may need to be changed. Tell your health care provider before you start taking any new medicine.

Common Side Effects

The most common side effect of AFINITOR is mouth ulcers and sores. When you start treatment with AFINITOR, 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 mouth gel that does not contain alcohol, hydrogen peroxide, iodine, or thyme.

Other common side effects of AFINITOR include:

• Infections
• Diarrhea
• Swelling of arms, hands, feet, ankles, face, or other parts of the body
• Feeling weak or tired
• Rash
• Cough
• Nausea
• Fever
• Decreased appetite
• Stomach-area [abdominal] pain
• Headache

Other side effects that may occur with AFINITOR:

• Absence of menstrual periods [menstruation]. You may miss 1 or more menstrual periods. Tell your health care provider if this happens
• AFINITOR 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. 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 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.