



# GETTING STARTED ON AFINITOR<sup>®</sup> (everolimus) Tablets

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Information for patients with gastrointestinal (GI)  
and lung neuroendocrine tumors (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.

Please click here for [full Prescribing Information](#) for AFINITOR, including [Patient Information](#).

Read this patient information before you start using AFINITOR® (everolimus) Tablets and each time you get a refill.

This information does not take the place of talking with your doctor about your condition or your treatment.



## WHAT IS AFINITOR?

AFINITOR® (everolimus) Tablets 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.



## WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AFINITOR?

**AFINITOR can cause serious side effects. These serious side effects include:**

- 1. 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
- 2. You may be more likely to develop an infection,** such as pneumonia, or a bacterial, fungal or viral infection. Viral infections may include active hepatitis B in people who have had hepatitis B in the past (reactivation). In some people (including adults and children) these infections may be severe, and can even lead to death. You may need to be treated as soon as possible.

Tell your 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
- Pain in the upper right side of the stomach

Please click here for [full Prescribing Information](#) for AFINITOR, including [Patient Information](#).



## WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AFINITOR? (cont)

- 3. Severe allergic reactions.** Severe allergic reactions can happen in people who take AFINITOR® (everolimus) Tablets. 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.
- 4. 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. 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.
- 5. You may develop kidney failure.** In some people this may be severe and can even lead to death. Your health care provider should do tests to check your kidney function before and during your treatment with AFINITOR.

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

See "What are the possible side effects of AFINITOR?" for more information about side effects.

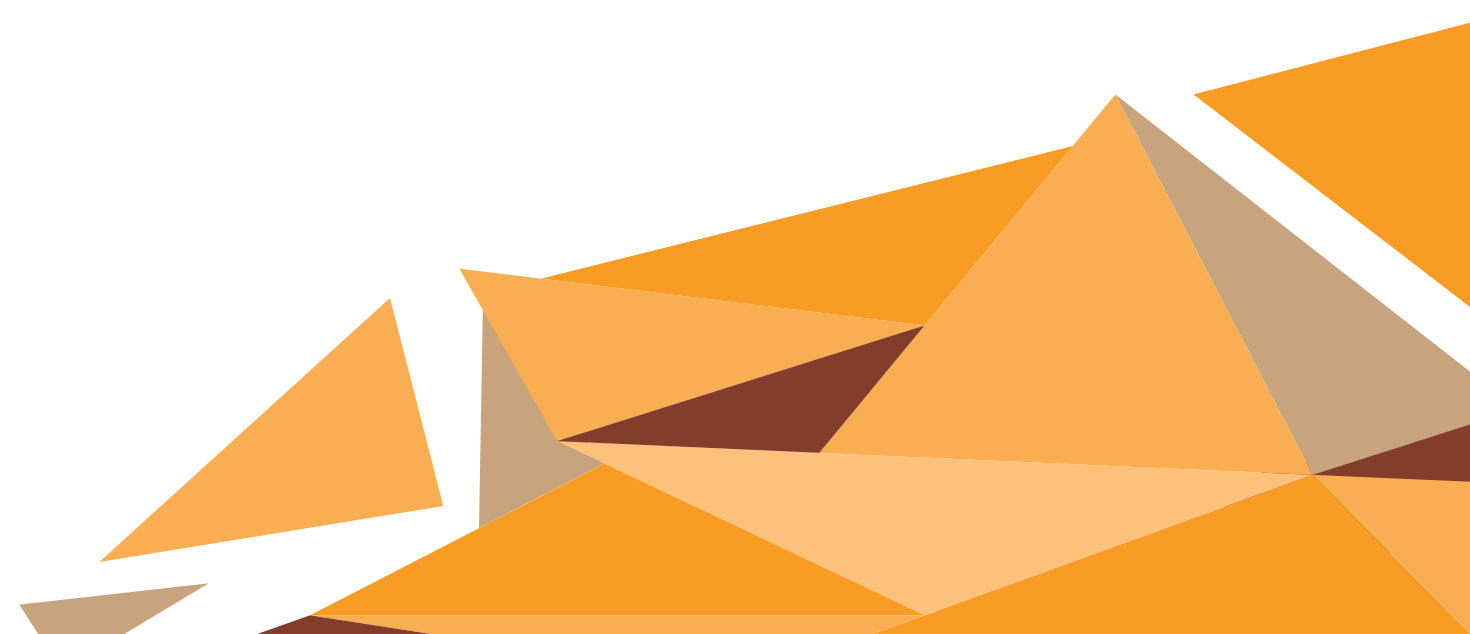


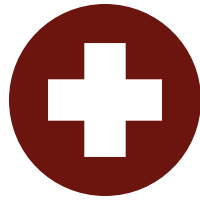
## HOW SHOULD I TAKE AFINITOR?

- Your health care provider will prescribe the dose of AFINITOR that is right for you
- Take AFINITOR exactly as your health care provider tells you to
- When you start treatment with AFINITOR, your health care provider may also prescribe 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
- Your health care provider may change your dose of AFINITOR or tell you to temporarily interrupt dosing, if needed
- **Take only AFINITOR or AFINITOR DISPERZ™ (everolimus tablets for oral suspension). Do not mix AFINITOR and AFINITOR DISPERZ together**
- Use scissors to open the blister pack

Please click here for [full Prescribing Information](#) for AFINITOR, including [Patient Information](#).

- Swallow AFINITOR tablets whole with a glass of water. Do not take any tablet that is broken or crushed
- Take AFINITOR 1 time each day at about the same time
- Take AFINITOR the same way each time, either 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
- 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 about what to do, call your health care provider
- 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





## WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE TAKING AFINITOR?

Before taking AFINITOR® (everolimus) Tablets, tell your health care provider about all of your medical conditions, including if you:

- Have or have had kidney problems
- Have or have had liver problems
- Have diabetes or high blood sugar
- 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 immunization or vaccine, ask your health care provider
- Are pregnant, can become pregnant, or have a partner who can become pregnant. AFINITOR can cause harm to your unborn baby. If you are a female who is able to become pregnant you should use effective birth control during treatment and for 8 weeks after your last dose of AFINITOR. If you are a male with a female partner, you should use effective birth control during treatment and for 4 weeks after your last dose of AFINITOR. Talk to your health care provider about birth control methods that may be right for you during this time. If you become pregnant or think you are pregnant, tell your health care provider right away
- Are breastfeeding or plan to breastfeed. It is not known if AFINITOR passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of AFINITOR
- Are planning to have surgery, if you have had a recent surgery, or if you have an unhealed wound. See “**What are the possible side effects of AFINITOR?**”
- Have high blood cholesterol levels
- Have any infections
- Previously had hepatitis B

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

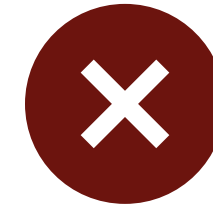
AFINITOR may affect the way other medicines work, and other medicines can affect how AFINITOR works. Taking AFINITOR with other medicines can cause serious side effects.

Know the medicines you take. Keep a list of them and show it to your health care provider and pharmacist when you get a new medicine. Especially tell your health care provider if you take:

- St. John’s Wort (*Hypericum perforatum*)
- Medicine for:
  - > Fungal infections
  - > Bacterial infections
  - > Tuberculosis
  - > Seizures
  - > HIV-AIDS
  - > Heart conditions or high blood pressure
- Medicines that weaken your immune system (your body’s ability to fight infections and other problems)

Please click here for [full Prescribing Information](#) for AFINITOR, including [Patient Information](#).

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



## WHAT SHOULD I AVOID WHILE TAKING AFINITOR?

You should not 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.



## WHO SHOULD NOT TAKE AFINITOR?

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

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

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

Ask your health care provider if you do not know.

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## WHAT ARE THE POSSIBLE SIDE EFFECTS OF AFINITOR?

**AFINITOR® (everolimus) Tablets can cause serious side effects.**

- See **“What is the most important information I should know about AFINITOR?”** for more information.
- **Delayed wound healing.** AFINITOR 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
  - > 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 the 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.

### **Common side effects include:**

- Mouth ulcers. AFINITOR can cause 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. If you develop pain, discomfort, or open sores in your mouth, tell your health care provider. Your health care provider may tell you to re-start this mouthwash or to use a special mouthwash or mouth gel that does not contain alcohol, peroxide, iodine, or thyme.
- Infections
- Rash
- Feeling weak or tired
- Diarrhea
- Swelling of arms, hands, feet, ankles, face or other parts of the body
- Stomach-area (abdominal) pain
- Nausea
- Fever
- Cough
- Headache
- Decreased appetite

Please click here for [full Prescribing Information](#) for AFINITOR, including [Patient Information](#).

### **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 may affect your ability to become pregnant. Talk to your health care provider if this is a concern for you.
- AFINITOR may affect fertility in males and may affect your 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. For more information, ask your health care provider or pharmacist.



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

### **General information about AFINITOR**

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

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

For more information call **1-888-423-4648** or go to [www.AFINITOR.com](http://www.AFINITOR.com)





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



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