

## I think of AFINITOR as hormone therapy PLUS — combined with exemestane, it gives me MORE.

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.





#### **Important Safety Information**

AFINITOR can cause serious side effects, including lung or breathing problems, infections, and kidney failure, which can lead to death.

AFINITOR can cause incisions to heal slowly or not heal well. Mouth ulcers and mouth sores are common side effects, occurring in up to 67% of advanced hormone receptor-positive, HER2-negative breast cancer patients taking AFINITOR. AFINITOR can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Regular blood tests should be performed before starting AFINITOR and as needed during treatment to check blood cell count, kidney and liver function, and blood sugar and cholesterol levels.

Exemestane is available in the US under the brand name Aromasin® from Pfizer. It is also available in generic form.

Please see Important Safety Information throughout this brochure and full Prescribing Information for AFINITOR, including Patient Information.



## The first treatment of its kind to be specifically approved for advanced hormone receptor-positive, HER2-negative breast cancer

AFINITOR® (everolimus) Tablets is a different approach to hormone therapy. When added to the hormone therapy exemestane, AFINITOR has been proven to extend the hormone therapy's benefits, more than doubling the time before cancer progressed compared to exemestane alone. The median progression-free period was 7.8 months with AFINITOR plus exemestane vs 3.2 months with exemestane alone. Currently available data have not shown an increase in overall survival. Additional data will be available in the future.

#### What is AFINITOR® (everolimus) Tablets?

AFINITOR 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. AFINITOR is offered in a once-daily oral tablet.

#### **Important Safety Information**

You should not take AFINITOR if you are allergic to AFINITOR or to any of its ingredients. You should tell your health care provider before taking AFINITOR if you are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

AFINITOR can cause serious side effects, such as lung or breathing problems, infections, or kidney failure. Some of these side effects 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.



# More OPTIOKS

Currently available data have not shown an increase in overall survival. Additional data will be available in the future.

## You have advanced HR+, HER2- breast cancer. What does this mean for you?

You've probably had conversations with your doctor about what it means to have advanced or metastatic breast cancer—when breast cancer has spread to lymph nodes around the breast or to other parts of the body. This includes stages III and IV.

Your doctor has most likely prescribed an important tumor test to determine if you are hormone receptor-positive (HR+), meaning that your breast cancer grows with the help of the hormones estrogen or progesterone. And, in most cases, your doctor will have determined whether or not your tumor has a high amount of a tumor marker called HER2.

A diagnosis of advanced HR+, HER2- breast cancer means you have advanced breast cancer and your tumors can respond to hormones, but they do not have abnormally high amounts of HER2 tumor markers

## Knowing your type of advanced breast cancer helps you set treatment goals with your doctor

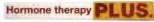
Knowing your hormone receptor status and your HER2 status is very important, since there are significantly different treatments for different types of advanced breast cancer.

If you have been diagnosed with advanced HR+, HER2- breast cancer, your doctor will use this information to create a plan designed to specifically treat your type of cancer. Together, you will discuss treatment options, set goals, and share important information, like:

- > Expectations when starting treatment
- ➤ How long you might be on treatment
- Frequency of checkups

- > Side effects concerns and discussions
- ➤ Follow-up tests







Currently available data have not shown an increase in overall survival. Additional data will be available in the future.

#### Hormone therapy in the treatment of advanced HR+ breast cancer

You may have discussed a type of treatment known as hormone therapy with your doctor. While there is currently no cure for advanced breast cancer, treatments such as hormone therapy may delay progression of the disease, allowing patients to live longer before their disease worsens. It's important to understand the difference between hormone therapy and hormone replacement therapy. Hormone replacement therapy refers to replacing a missing hormone in people who need it. Hormone therapy usually means treatment to limit the ways that the cancer can benefit from hormones.

#### **Understanding hormone therapy**

There are different types of hormone therapy used to treat advanced HR+ breast cancer. Some block estrogen from binding to the tumor, and others work by limiting the production of estrogen in the body. Aromatase inhibitors are one type of hormone therapy. Your doctor may prescribe 1 of 3 different aromatase inhibitors for you: letrozole, anastrozole, or exemestane.\*

As you may have heard or even experienced, hormone therapy can stop working over time, and the cancer may progress. When this happens, the cancer is said to be "resistant" to hormone treatment. Often you will be given another type of hormone therapy and will stay on that treatment until you become resistant again.

#### AFINITOR® (everolimus) Tablets helps extend your time on hormone therapy

AFINITOR® (everolimus) Tablets, when added to the hormone therapy exemestane, has been proven to extend the hormone therapy's benefits, more than doubling the time before cancer progression compared to exemestane alone. The median progression-free period was 7.8 months with AFINITOR plus exemestane vs 3.2 months with exemestane alone.

If you have previously been on letrozole or anastrozole, AFINITOR plus exemestane might be right for you.







#### **How AFINITOR works**

AFINITOR does not work in the same way that hormone therapy and chemotherapy do.

- > AFINITOR targets a specific pathway that may help address cancer's resistance to hormone therapy
- ➤ AFINITOR works in combination with the hormone therapy exemestane to help stop the growth of advanced or metastatic HR+, HER2- breast cancer
- ➤ AFINITOR also affects noncancerous cells
- ➤ Although AFINITOR has been studied in patients with HR+, HER2- breast cancer, how AFINITOR works has only been demonstrated in laboratory studies

Combining AFINITOR with exemestane makes sense as a treatment strategy to potentially address advanced breast cancer's resistance to hormone therapy. Currently available data have not shown an increase in overall survival. Additional data will be available in the future.

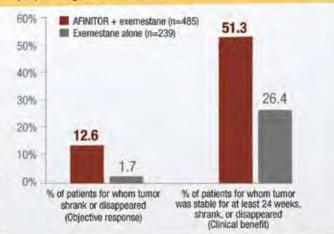
#### **Important Safety Information**

AFINITOR may make you 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. 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, 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.

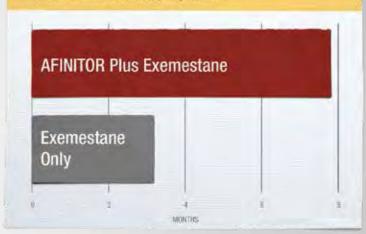


More people taking AFINITOR with exemestane had tumors that shrank or disappeared, or were stable for at least 24 weeks, than people taking exemestane alone



- ➤ 3 patients (0.6%) had a complete response (tumor disappeared) with AFINITOR + exemestane
- ➤ 58 patients (12.0%) had a partial response (tumor shrank) with AFINITOR + exemestane
- ➤ No patients (0%) had a complete response with exemestane alone
- > 4 patients (1.7%) had a partial response with exemestane alone

#### Time without disease progression



The median progression-free period was 7.8 months with AFINITOR plus exemestane vs 3.2 months with exemestane alone.

## Why consider AFINITOR® (everolimus) Tablets?

For postmenopausal women who progressed on other hormone therapies (letrozole or anastrozole), AFINITOR® (everolimus) Tablets, in combination with exemestane, more than doubled the time of progression-free survival (the amount of time patients lived without their tumors growing) compared to patients who took only exemestane.\* The median progression-free period was 7.8 months with AFINITOR plus exemestane vs 3.2 months with exemestane alone.

- ➤ Twice as many people taking AFINITOR with exemestane experienced shrinkage or disappearance of tumors or stable disease (51.3% of people taking AFINITOR with exemestane compared to only 26.4% of people taking exemestane alone)
- ➤ Tumors shrank in 12.6% of people taking AFINITOR with exemestane compared to 1.7% in people taking exemestane alone

Currently available data have not shown an increase in overall survival. Additional data will be available in the future.

## AFINITOR combined with exemestane gives you more.

More out of your hormone treatment. More time before progression. More options.

\*Letrozole is available in the US under the brand name Femara® from Novartis and anastrozole is available in the US under the brand name of Arimidex® from AstraZeneca. Exemestane is available in the US under the brand name Aromasin® from Pfizer. These aromatase inhibitors are also available in generic form.

#### What are the potential risks of AFINITOR with exemestane?

You should not take AFINITOR if you are allergic to AFINITOR or to any of its ingredients. You should tell your health care provider before taking AFINITOR if you are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

AFINITOR can cause serious side effects, such as lung or breathing problems, infections, or kidney failure. Some of these side effects 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: You should 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.

**Infections:** AFINITOR may make you 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. 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, 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.

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

The most common side effect of AFINITOR in treating advanced hormone receptor-positive, HER2-negative breast cancer was mouth ulcers and sores (67%). Tell your health care provider if you have pain, discomfort, or open sores in your mouth. Your health care provider may tell you to use a special mouthwash or mouth gel that does not contain alcohol, hydrogen peroxide,

#### Other common side effects of AFINITOR include:

➤ Infections (50%)

**Common Side Effects** 

> Rash (39%)

iodine, or thyme.

- > Feeling tired (36%)
- ➤ Diarrhea (33%)
- ➤ Loss of appetite (30%)
- ➤ Nausea (29%), vomiting (17%)
- ➤ Weight loss (25%)
- ➤ Cough (24%), shortness of breath (21%)
- ➤ Abnormal taste (22%)
- ➤ Headache (21%)
- ➤ Pain in arms and legs (9%), back (14%), joints (20%)
- > Swelling of arms, hands, feet, ankles, face, or other parts of the body (19%)
- ➤ Nose bleeds (17%)
- ➤ Fever (15%)
- ➤ Constipation (14%)
- ➤ High blood glucose (14%)
- ➤ Difficulty sleeping (13%)
- > Feeling weak (13%)
- ➤ Itching (13%)
- > Dry mouth (11%)
- ➤ Hair loss (10%)

The brands listed are the trademarks or register marks of their respective owners and are not the trademarks or register marks of Novartis.

Please see Important Safety Information throughout this brochure and full Prescribing Information for AFINITOR, including Patient Information.







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

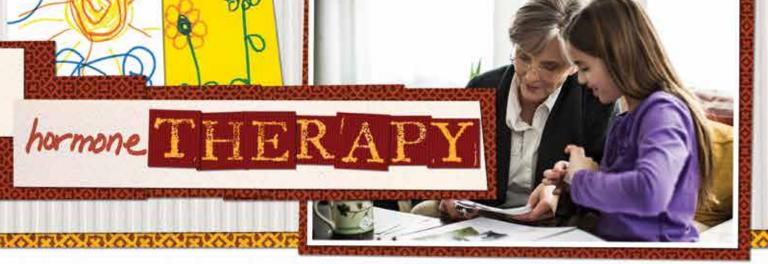
## What should I avoid while taking

You should not drink grapefruit juice or eat grapefruit during your treatment with AFINITOR. It may make the amount of AFINITOR in your blood



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 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, 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.

Use scissors to open the blister pack.



## What to expect when starting AFINITOR

AFINITOR works differently from other treatments you may have had in the past, so it may cause some side effects you are not familiar with. That's why it's important to work together with your health care team to create a plan for managing side effects. They can identify which side effects are most likely to happen and which are not. Be sure to discuss any concerns you have about side effects, as well as any side effects you notice during treatment.

#### Ask your doctor:

- What are the most serious side effects that may occur during treatment with AFINITOR?
- ➤ What side effects are most likely during and after treatment with AFINITOR?
- ➤ How might side effects be managed or treated?

Side effects while taking AFINITOR can vary from patient to patient. Not everyone will experience the same side effects or the same degree of severity. If you experience side effects, please talk with your doctor about possible dose adjustments based on the severity to see how you may be able to stay on AFINITOR.

## Helping you start and stay on treatment through dose adjustments

We understand that being able to stay on treatment is important to you. That's why it is important to report your symptoms early to your doctor or nurse.

Your doctor or nurse may be able to adjust your dose or temporarily stop treatment until your symptoms improve. Flexible dosing can be a normal part of treatment, and it helps your doctor find the dosage strength of AFINITOR 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.

If your dose is changed, AFINITOR offers a free 14-day trial so you can start seamlessly at your new dose without additional co-pay costs.

Please talk to your doctor or nurse for more information on how to access this program.

Please see Important Safety Information throughout this brochure and full Prescribing Information for AFINITOR, including Patient Information.

# Ways to be proactive

#### Mouth sores: what to look out for

Mouth sores and ulcers are one of the most common side effects of AFINITOR® (everolimus) Tablets. Mouth sores can appear as early as within the first 2 weeks of treatment or can occur at any time during treatment.

Be sure to contact your doctor or nurse immediately if you have any of the following symptoms in your mouth, lips, gums, or throat:

- Sensations of tenderness, swelling, tingling, pain, or burning
- ➤ Difficulty eating spicy food
- Changes in or difficulty with eating, drinking, or swallowing

Sores/redness

Call your doctor or nurse as soon as you experience any of these symptoms. They could be early signs that you are developing mouth sores.







#### Tips your doctor may provide

Before starting AFINITOR, and during treatment, your doctor may offer some suggestions about proper oral care and what foods to avoid.

Don't eat foods that you are allergic to, and keep in mind any dietary restrictions you may have. Talk to your doctor if you have any questions or concerns.

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mild to
Try to
Floss r
Rinse
salt wa

Take good care of your mouth and visit your dentist regularly
Use a soft-bristled toothbrush and mild toothpaste
Try to brush after every meal
Floss regularly

Eat soft foods (such as milkshakes, smoothies,

pudding, yogurt, mashed potatoes, or bananas)

Rinse your mouth several times a day with a salt water mixture

Your doctor or nurse may also provide you with prescription treatment options that may help treat mouth sores. 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)

Avoid drinking hot liquids or beverages

Don't use a mouthwash that contains alcohol, hydrogen peroxide, iodine, or thyme because it may irritate your mouth. Check with a doctor, nurse, or pharmacist before using a store-bought mouthwash DON'TS

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Having advanced HR+, HER2- breast cancer isn't easy, but we want you to know you're not alone. That's why we've created a comprehensive support program that gives you more of the help you need on your breast cancer journey.



#### **M**eaningful help

With the AFINITOR® (everolimus) Tablets Co-Pay Card, most eligible patients pay no more than \$25 per month for their AFINITOR prescription. There's also financial help available through Patient Assistance NOW Oncology for insured and uninsured patients alike.



#### **O**pen communications

The M.O.R.E. Network brings live educational programs to your area so you can hear from advanced breast cancer experts and patients and learn more about treatment with AFINITOR.



#### Resources

M.O.R.E. Nurse Connect provides you with a personal connection to an oncology nurse who can answer your questions and assist you with the challenges you may encounter throughout your treatment journey.



#### Education

Helpful materials like this brochure, the Dosing Card, and our Caregiver Guide are available to download at www.MORE-AFINITOR.com.



### M.O.R.E. Live support for your treatment questions

As you go through your treatment journey, you may have questions from time to time, and you may not always be able to reach your doctor. In these moments, you can call M.O.R.E. Nurse Connect. Assistance is available 24/7 in 137 languages.



#### The M.O.R.E. Nurse Connect Program can:

Answer your treatment questions, including how to take AFINITOR correctly Offer lifestyle and side effect information

Assist with many of the other questions you may have along the way

Call 1-855-767-8287 anytime, 24 hours a day, 7 days a week.

The M.O.R.E. Nurse Connect Program does not replace talking with your doctor about your treatment.



## M.O.R.E. Providing treatment education for patients with advanced breast cancer

The M.O.R.E. Network is a series of live educational events that feature experts in the field of advanced breast cancer, as well as patients living with advanced HR+, HER2- breast cancer. At M.O.R.E. Network presentations, you'll learn about:

- ➤ Advanced/metastatic breast cancer
- ➤ The role of hormone therapy
- > Treatment with AFINITOR
- Support programs provided by the makers of AFINITOR to assist you during treatment
- Communicating and partnering with your health care team

## When is the next M.O.R.E. Network event in my area?

These events take place at a variety of times and locations across the United States.

**Call 1-866-866-9303** to find an educational event in your area.





#### The AFINITOR® (everolimus) Tablets Co-Pay Card

Novartis Pharmaceuticals Corporation is committed to helping make treatment with AFINITOR® (everolimus) Tablets as affordable as possible. For patients with commercial insurance, we offer the AFINITOR Co-Pay Card, which provides eligible patients with a way to lower out-of-pocket costs for their treatment.

## How may the AFINITOR Co-Pay Card help with my out-of-pocket costs?

## Most eligible patients pay no more than \$25 a month for AFINITOR with the AFINITOR Co-Pay Card.

For most eligible patients, the co-pay for your AFINITOR prescription will be no more than \$25 for each 28-day prescription. Novartis will pay the remainder of your co-pay for AFINITOR, up to a maximum of \$6350 per month. This program expires on December 31, 2014.



Here's an example of how the costs are broken down:		
If your insurance co-pay is:	\$1000	
Novartis pays:	\$975	
You pay:	\$25	



#### Am I eligible for the AFINITOR Co-Pay Card?

Answer these statements to see if you may be eligible.

I am covered by commercial insurance	Yes	■ No
I am NOT on Medicare, Medicaid, or any other government-funded health care program	Yes	■ No
I am a postmenopausal woman who has already taken letrozole or anastrazole and have been prescribed AFINITOR together with exemestane to treat advanced HR+, HER2- breast cancer	Yes	□ No
I live in the United States or Puerto Rico	Yes	□ No
If you answered "yes" to all 4 statements above, you may be eligible for the AFINITOR Co-Pay Card		

Additional limitations may apply.

#### What if I'm not eligible for the AFINITOR Co-Pay Card?

If you answered "no" to any of the above statements or if you are otherwise ineligible for the co-pay card, there are other ways we can help to make treatment with AFINITOR as affordable as possible. See the information on our Patient Assistance NOW Oncology support programs on pages 16 and 17.

#### How do I get my AFINITOR Co-Pay Card?

You can download the AFINITOR Co-Pay Card at www.MORE-AFINITOR.com.





#### Helping to make access to the therapies you need easier

Novartis Oncology is committed to helping patients living with cancer receive the medicines they need. **Patient Assistance NOW Oncology** offers quick and easy access to information about the broad array of support and reimbursement programs available.

## You can get information about our Patient Assistance NOW Oncology support programs in two ways:

- Call **1-800-282-7630** to speak to one of our knowledgeable staff, who are dedicated to making access to our programs as simple as possible
- Visit our website at www.PatientAssistanceNow.com/oncology

#### **Support for Patients Includes:**

- Insurance verification
- Medicare education
- Assistance with denials/appeals
- Therapy-specific support programs for out-of-pocket costs
- Assistance searching for other sources of coverage/funding that could alleviate or reduce costs for patients
- Referrals to independent charitable foundations for assistance with co-pay costs
- Patient assistance for low-income and uninsured patients

#### Am I eligible for Patient Assistance NOW Oncology support?

All patients who have been prescribed AFINITOR® (everolimus) Tablets for a Food and Drug Administration-approved use may be eligible for **Patient Assistance NOW Oncology**, whether you have commercial insurance, government-funded insurance—or even if you have no insurance at all. Contact **Patient Assistance NOW Oncology** to find out what services may be available to you.





#### How do I enroll?

To enroll in **Patient Assistance NOW Oncology**, you and your doctor will need to fill out the appropriate forms and submit them to your health insurance. There are 3 ways to get these enrollment forms.

- Online at www.PatientAssistanceNow.com/oncology
- By calling 1-800-282-7630
- By asking your doctor about Patient Assistance NOW Oncology

#### If you're insured, you may be eligible for:

- Novartis Patient Assistance NOW Oncology Hotline: 1-800-282-7630
- Reimbursement services
- Options for patients with high co-pay obligations
- Co-pay support from independent charitable foundations
- Therapy-specific support programs for out-of-pocket costs

## If you're not insured, you may be eligible for:

- Novartis Patient Assistance Program: 1-866-884-5906
- Novartis therapy-specific support programs
- Medicare Part D enrollment assistance

#### **Additional Safety Information**

Before taking AFINITOR® (everolimus) Tablets, 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 immunization or vaccine, ask your health care provider

- > Have other medical conditions
- ➤ Are pregnant or could become pregnant. AFINITOR can cause harm to your unborn baby. You should use effective birth control while using AFINITOR and for 8 weeks after stopping treatment. Talk to your health care provider about birth control options while taking AFINITOR
- Are breastfeeding or plan to breastfeed. You and your health care provider should decide if you will take AFINITOR or breastfeed. You should not do both

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

➤ Tuberculosis

> HIV-AIDS

➤ Bacterial infections

➤ Seizures

> 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.

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 see <u>full Prescribing Information for AFINITOR</u>, <u>including Patient Information</u>.





#### **M**eaningful help

Get savings and financial help through the AFINITOR® (everolimus) Tablets Co-Pay Card and Patient Assistance NOW Oncology.



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