

AFINITOR[®] TABLET

Everolimus (5mg, 10mg)

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What is AFINITOR used for?

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.
- Adults with a type of pancreatic cancer known as pancreatic neuroendocrine tumor (PNET) that has progressed and cannot be treated with surgery.
- 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.
- Adults with advanced kidney cancer (renal cell carcinoma or RCC) when certain other medicines have not worked.
- People with the following types of tumors that are seen with a genetic condition called tuberous sclerosis complex (TSC):
 - Adults with a kidney tumor called angiomyolipoma, when their kidney tumor does not require surgery right away.
 - Adults and children 1 year of age and older with a brain tumor called subependymal giant cell astrocytoma (SEGA) when the tumor cannot be

removed completely by surgery.

How Afinitor works

Treatment of hormone receptor-positive advanced breast cancer

Growth of this type of breast cancer is stimulated by estrogens which are female sex hormones. Aromatase inhibitors reduce the amount of estrogen and can slow the growth of breast cancers. Taking AFINITOR together with an aromatase inhibitor also prevents breast cancer cells from becoming resistant to the hormonal therapy, which may consequently reduce the growth of breast cancers and delays breast cancer recurrences.

Treatment of advanced neuroendocrine tumors

Neuroendocrine tumors are rare tumors which can be found in different parts of the body. AFINITOR may control the growth of these tumors located in the stomach and intestine, lung or pancreas.

Treatment of advanced kidney cancer

AFINITOR may stop the cancer from making new cells and may cut off the blood supply to the cancer. This may slow down the growth and spread of kidney cancer.

Treatment of TSC with angiomyolipoma of the kidney

AFINITOR may reduce the size of angiomyolipoma of the kidney that is associated with a genetic disorder called tuberous sclerosis complex (TSC). This may lower the risk of the tumor(s) causing bleeding complications and may help to preserve kidney function.

Treatment of TSC with SEGA

AFINITOR may reduce the size of brain tumors (SEGA) that are caused by a genetic disorder called tuberous sclerosis (TSC). This may lower the risk of the tumors causing problems as they grow, such as hydrocephalus (excessive accumulation of fluid within the brain).

Before you use Afinitor

When you must not use it

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

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

- a medicine that contains sirolimus
- a medicine that contains temsirolimus

Ask your healthcare provider if you do not know.

Pregnancy and lactation

Tell your healthcare provider right away if you are pregnant, can become pregnant or have a partner who can become pregnant. AFINITOR can cause harm to your unborn baby.

Tell your healthcare provider if you 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.

Before you start to use it

Before taking AFINITOR, tell your healthcare 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
- 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 healthcare provider.
- For children with TSC and SEGA, work with your healthcare provider to complete the recommended childhood series of vaccines before your child starts treatment with AFINITOR.

- Are planning to have surgery, if you have had a recent surgery. You should stop taking AFINITOR at least 1 week before planned surgery. See 'Side Effects'.
- Have received radiation therapy or are planning to receive radiation therapy in the future. See 'Side Effects'.
- Heart conditions or high blood pressure
- Medicines that weaken your immune system (your body's ability to fight infections and other problems)

Ask your healthcare 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 healthcare provider might need to prescribe a different medicine or your dose of AFINITOR may need to be changed. You should also tell your healthcare provider before you start taking any new medicine.

How to use Afinitor

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

How much to use

Your healthcare provider will prescribe the dose of AFINITOR that is right for you.

- Take AFINITOR exactly as your healthcare provider tells you to.
- Your healthcare provider may change your dose of AFINITOR or tell you to temporarily interrupt dosing, if needed. Use scissors to open the blister pack.

When to use it

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

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

How long to use it

Continue taking AFINITOR as long as your doctor tells you.

If you forget to use it

If you miss a dose of AFINITOR, you may still 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 the one that you missed. If you are not sure about what to do, call your healthcare provider.

If you use more Afinitor than you should (overdose)

If you take too much AFINITOR, contact your healthcare provider or go to the nearest hospital emergency department right away. Take the pack of AFINITOR with you.

While you are using Afinitor

Things you must do

- 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.
- If you take AFINITOR to treat SEGA, you will also need to have blood tests regularly to measure how much medicine is in your blood. This will help your healthcare provider decide how much AFINITOR you need to take.

Things you must not do

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.

Things to be careful of

You may develop lung or breathing problems. In some people, lung or breathing problems may be severe and can lead to death. Tell your healthcare 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 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 lead to death. You may need to be treated as soon as possible.

Tell your healthcare provider right away if you have a temperature of

Contraception

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with AFINITOR.
- You should use effective birth control during treatment and for 8 weeks after your last dose of AFINITOR.

Males 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 healthcare 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 healthcare provider right away.

Taking other medicines

Tell your healthcare 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 work. 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 healthcare provider and pharmacist when you get a new medicine. Especially tell your healthcare provider if you take:

- St. John's Wort (*Hypericum perforatum*)
- Medicine for:
 - Fungal infections
 - Bacterial infections
 - Tuberculosis
 - Seizures
 - HIV-AIDS

100.5°F (38°C) 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 swelling
- Tiredness
- Loss of appetite
- Nausea
- Pale stools or dark urine
- Yellowing of the skin
- Pain in the upper right side of the stomach

Severe allergic reactions. Call your healthcare 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. Talk with your healthcare 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.

Mouth ulcers and sores. Mouth ulcers and sores are common during treatment with AFINITOR but can also be severe. When you start treatment with AFINITOR, your healthcare 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 healthcare provider's instructions on how to use this prescription mouthwash. If you develop pain, discomfort, or open sores in your mouth, tell your healthcare provider. Your healthcare 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.

You may develop kidney failure. In some people this may be severe and

can lead to death. Your healthcare 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 healthcare provider's instructions.

Side effects

Risk of wound healing problems.

Wounds may not heal properly during AFINITOR treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with AFINITOR.

- You should stop taking AFINITOR at least 1 week before planned surgery.
- Your healthcare provider should tell you when you may start taking AFINITOR again after surgery.

Increased blood sugar and fat (cholesterol and triglyceride) levels in the blood. Your healthcare 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 healthcare provider should do blood tests to check your blood cell counts before you start and during treatment with AFINITOR.

Worsening side effects from radiation treatment, that can sometimes be severe. Tell your healthcare provider if you have had or are planning to receive radiation therapy.

The most common side effects of AFINITOR in people with advanced hormone receptor-positive, HER 2-negative breast cancer, advanced neuroendocrine tumors of the pancreas, stomach and intestine (gastrointestinal) or lung, and advanced kidney cancer include:

- 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

The most common side effects of AFINITOR in people who have SEGA or renal angiomyolipoma with TSC include respiratory tract infections.

Other side effects that may occur with AFINITOR:

- Absence of menstrual periods (menstruation). You may miss one or more menstrual periods. Tell your healthcare provider if this happens.
- AFINITOR may affect fertility in females and may affect your ability to become pregnant. Talk to your healthcare 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 healthcare provider if this is a concern for you.

Tell your healthcare 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 healthcare provider or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Afinitor

- Storage

- Do not store above 30°C.
- Store in original packaging in order to protect from light and moisture.
- Open the blister pack just before taking AFINITOR.

- Keep AFINITOR away from light.
- Do not use AFINITOR that is out of date or no longer needed.
- Keep AFINITOR and all medicines out of the reach of children.

Damansara Uptown,
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Information Issued
31/05/2021 and USPI 02/2022

Date of revision
19 May 2026

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Serial Number
NPRA (R1/5) 18052022/134

Product Description

What it looks like

AFINITOR Tablets

The tablets are white to slightly yellowish, elongated with a bevelled edge and no score.

Each 5 mg tablet contains 5 mg *everolimus* and is engraved with “5” on one side and “NVR” on the other.

Each 10 mg tablet contains 10 mg *everolimus* and is engraved with “UHE” on one side and “NVR” on the other.

Ingredients

AFINITOR

- *Active ingredients*
The active substance of AFINITOR is *everolimus*.
- *Inactive ingredients*
The other ingredients are *anhydrous lactose, butylated hydroxytoluene, crospovidone, hypromellose, lactose monohydrate, and magnesium stearate*.

MAL Number

Afinitor 5mg tablet
(MAL20091942ARZ)
Afinitor 10mg tablet
(MAL20091943ARZ)

Manufacturer

Novartis Pharmaceuticals S.R.L.
Str. Livezeni nr. 7A
540472 Targu Mures
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Product Registration Holder

Novartis Corporation (Malaysia)
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