

NOW AVAILABLE





AFINITOR[®] (everolimus) tablets

Indication

- Afinitor is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib
- Please see Important Safety Information Below

How to order Afinitor

- To order Afinitor, call ASD Healthcare at 1-800-746-6273 or visit them online at www.asdhealthcare.com
—ASD Healthcare can bill the wholesaler; the wholesaler can bill the pharmacy; or ASD Healthcare can bill you directly
- ASD Healthcare will ship product overnight

How Supplied	NDC Number	Quantity
 <p>28 Tablets Each tablet contains 10 mg of everolimus. AFINITOR[®] (everolimus) tablets 10 mg NOVARTIS</p> <p>(recommended dosage)</p>	NDC 0078-0567-51	28 tablets
 <p>28 Tablets Each tablet contains 5 mg of everolimus. AFINITOR[®] (everolimus) tablets 5 mg NOVARTIS</p>	NDC 0078-0566-51	28 tablets

Drug-drug interactions

- Avoid concurrent treatment with strong or moderate CYP3A4 or PgP inhibitors and strong CYP3A4 inducers
- If Afinitor must be co-administered with strong CYP3A4 inducers, consider increasing the Afinitor dose from 10 mg daily up to 20 mg daily using 5-mg increments

For more information about Afinitor, call 1-888-4Afinitor (1-888-423-4648) or visit www.AFINITOR.com.
For reimbursement questions, call 1-888-5AfiniTRAC (1-888-523-4648).

Common Patient Questions

How should Afinitor be taken?

- Swallow Afinitor tablets whole with a glass of water. Do not crush or chew the tablets. If you cannot swallow Afinitor tablets whole, tell your healthcare provider
- Take Afinitor each day, at about the same time, with or without food
- Do 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

What are the possible side effects of Afinitor?

Common side effects include:

- Mouth ulcers
- Infections
- Feeling weak or tired
- Cough, shortness of breath, and lung or breathing problems
- Diarrhea
- Rash, dry skin, and itching
- Nausea and vomiting
- Fever
- Loss of appetite
- Swelling of arms, hands, feet, ankles, face or other parts of the body
- Abnormal taste
- Inflammation of lining of the digestive system
- Headache
- Nose bleeds
- Pain in arms and legs

Possible serious side effects include:

- Lung or breathing problems (pneumonitis)
- Infections

Patients should contact their physician if they experience any of the above effects.

How should Afinitor be stored?

- Store Afinitor in the original package at room temperature (59° to 86° F/15° to 30° C)
- Protect the tablets from light and moisture
- Open blister package just prior to taking the medication; use scissors to open blister

Important Safety Information

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients. Non-infectious pneumonitis is a class effect of rapamycin derivatives, including Afinitor. Fatal outcomes have been observed. If symptoms are moderate or severe, patients should be managed with dose interruption until symptoms improve or discontinuation, respectively. Corticosteroids may be indicated. Afinitor may be reintroduced at 5 mg daily depending on the individual clinical circumstances.

Afinitor has immunosuppressive properties and may predispose patients to infections. Localized and systemic infections (bacterial and invasive fungal infections) have occurred. Some of these infections have been severe or fatal. Complete treatment of pre-existing invasive fungal infections prior to starting treatment. If a diagnosis of invasive systemic fungal infection is made, discontinue Afinitor and treat with appropriate antifungal therapy.

Oral ulcerations have occurred in patients treated with Afinitor. In such cases, topical treatments are recommended, but alcohol- or peroxide-containing mouthwashes should be avoided. Antifungal agents should not be used unless fungal infection has been diagnosed.

Elevations of serum creatinine, glucose, lipids, and triglycerides and reductions of hemoglobin, lymphocytes, neutrophils and platelets have been reported in clinical trials. Renal function, hematological

parameters, blood glucose, and lipids should be evaluated prior to treatment and periodically thereafter. When possible, optimal glucose and lipid control should be achieved before starting a patient on Afinitor. Co-administration with strong or moderate inhibitors of CYP3A4 or P-gP should be avoided. Increase in the Afinitor dose is recommended when co-administered with a strong CYP3A4 inducer.

Afinitor should not be used in patients with severe hepatic impairment. The use of live vaccines and close contact with those who have received live vaccines should be avoided during treatment with Afinitor. Fetal harm can occur if Afinitor is administered to a pregnant woman. The most common adverse reactions (incidence $\geq 30\%$) were stomatitis, infections, asthenia, fatigue, cough, and diarrhea. The most common grade 3/4 adverse reactions (incidence $\geq 3\%$) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain, and asthenia. The most common laboratory abnormalities (incidence $\geq 50\%$) were anemia, hypercholesterolemia, hypertriglyceridemia, hyperglycemia, lymphopenia, and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence $\geq 3\%$) were lymphopenia, hyperglycemia, anemia, hypophosphatemia, and hypercholesterolemia. Deaths due to acute respiratory failure (0.7%), infection (0.7%), and acute renal failure (0.4%) were observed on the Afinitor arm.

Please see full Prescribing Information.

