

April, 2009

ATT: PHARMACEUTICAL BUYER

DEAR VALUED CUSTOMER:

PRODUCT INTRODUCTION
Afinitor[®] (everolimus) 5 mg and 10 mg tablets

Novartis Pharmaceuticals Corporation is pleased to announce the introduction of Afinitor[®] (everolimus) tablets, approved by the FDA on March 30, 2009. Afinitor is a once-daily oral mTOR inhibitor 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. Afinitor is available by prescription only and is packaged in a blister card.

KEY PRODUCT/PACKAGING INFORMATION:

	FG # 714573	FG # 714570		
	Afinitor 5 mg 28's	Afinitor 10 mg 28's	Afinitor 5 mg 7's (not for resale)	Afinitor 10 mg 7's (not for resale)
NDC Number	0078-0566-51	0078-0567-51	0078-0566-61	0078-0567-61
Package Strength	5 mg	10 mg	5 mg	10 mg
Package Size	28 tablets	28 tablets	7 tablets	7 tablets
Package Dimensions (L x W x H)	5-1/16" x 1-7/16" x 1-3/8"	5-1/16" x 1-7/16" x 1-3/8"	N/A	N/A
Package Weight	0.09 lbs	0.11 lbs	N/A	N/A
Minimum Order Requirement	No minimum	No minimum	N/A	N/A
Case Weight	2.5 lbs	2.9 lbs	N/A	N/A
Case Dimensions (L x W x H)	13-1/4" x 6-7/8" x 5- 1/2"	13-1/4" x 6-7/8" x 5- 1/2"	N/A	N/A
Case Count	18	18	N/A	N/A

All pharmacies are able to order and dispense Afinitor. Because the drug is appropriate for only a small number of patients, it will be available only through a specialty distributor, ASD Specialty Healthcare, Inc. (ASD). ASD will sell and distribute the drug through an "Afinitor Depot."

Orders must be placed directly with ASD by calling 1-800-746-6273, faxing an ASD order form to 1-800-547-9413, or placing the order at www.asdhealthcare.com.

The Afinitor Depot is an ongoing product support operation that facilitates "open channel" pharmacy access to Afinitor. Novartis decided to use this managed distribution system, which provides strong inventory control, because advanced renal cell carcinoma is a relatively rare and difficult disease to treat. In 2008, there were approximately 54,390 new cases of kidney cancer and 13,010 deaths according to the Kidney Cancer Association.¹

Pharmacies will have 2 billing options through the Afinitor Depot:

- 1. Billing through your designated primary wholesaler:** Some wholesalers will establish or have agreements with ASD to sell Afinitor by drop-ship/bill-through with a designated wholesaler. Pharmacies preferring this method of purchase should confirm their designated wholesaler has such an agreement with ASD. ASD can only drop ship once approval has been received by the wholesaler. (Each order may require an approval.)
- 2. Ordering/billing directly through ASD:** Pharmacies must have or establish an account with ASD to order the drug through the Afinitor Depot. Instructions for opening an account will be provided by ASD upon placing the initial order.



Afinitor is indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib.

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 PgP 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.

If you have any questions, please contact Novartis Pharmaceuticals Corporation at 1-888-4Afinitor (1-888-423-4648).

As always, thank you for your continued support of Novartis Pharmaceuticals Corporation.

Sincerely,

Michael A. Conley, Executive Director
U.S. Managed Markets, Trade

If you prefer to opt out of receiving product notifications from Michael Conley/Novartis Pharmaceuticals Corporation and be removed from this fax list, please contact Dolores Urban by calling 1-888-644-8585, extension 27982 or 1-862-778-7982, or e-mail dolores.urban@novartis.com, or by faxing an opt-out request to fax number 973-781-6782.

Reference: 1. American Cancer Society 2008. <http://www.cancer.org>.

Please see full Prescribing Information.

