

## CONSUMER INFORMATION

### Pr **AFINITOR\*** (everolimus tablets)

**This leaflet is part III of a three-part “Product Monograph” published when AFINITOR\* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AFINITOR\*. Contact your doctor or pharmacist if you have any questions about the drug.**

Keep this leaflet. You may need to read it again. This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

AFINITOR\* is used in the treatment of metastatic kidney cancer (when cancer cells have spread from the kidney to other parts of the body) after failure of treatment with sunitinib or sorafenib. It is not known whether AFINITOR\* prolongs overall survival or improves the quality of life of patients with kidney cancer.

#### **What it does:**

Everolimus in AFINITOR\* works by blocking a specific enzyme that is involved in tumour cell growth and division. This helps to slow down the growth and spread of kidney cancer cells.

#### **When it should not be used:**

If you are allergic (hypersensitive) to everolimus, or sirolimus (RAPAMUNE®), temsirolimus (TORISEL®), or any of the other ingredients in AFINITOR\* listed below in the *What the important nonmedicinal ingredients are* section.

#### **What the medicinal ingredient is:**

Everolimus.

#### **What the important nonmedicinal ingredients are:**

Butylated hydroxytoluene (E321), magnesium stearate, lactose monohydrate, hypromellose, croscopovidone and lactose anhydrous.

#### **What dosage forms it comes in:**

AFINITOR\* is supplied as 5 and 10 mg tablets that 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.

Each blister pack contains 10 tablets and there are 3 blister packs in a carton.

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

AFINITOR\* should be prescribed and managed only by a doctor experienced in anticancer drugs.

AFINITOR\* has not been studied in patients with severely reduced liver function.

Serious side effects which have been reported with the use of AFINITOR\* include:

- Non-infectious pneumonitis (including interstitial lung disease)
- Infections

### **BEFORE you use AFINITOR\* talk to your doctor or pharmacist if you:**

- have any problems with your liver or have previously had any liver disease
- have any infections
- have had hepatitis B, because it may be reactivated during your treatment with AFINITOR\*
- have diabetes (high level of glucose in the blood)
- have high cholesterol or triglyceride levels
- have low blood cell count
- are going to have surgery. AFINITOR\* might affect the way your wound heals.
- are pregnant, think you may be pregnant, or are planning to become pregnant
- are breastfeeding
- need to receive a vaccine

AFINITOR\* is not to be used in children or adolescents under 18 years of age.

### **What you should know during AFINITOR\* treatment**

- if during treatment with AFINITOR\* you develop symptoms such as swelling of the airways or tongue and/or difficulty breathing, these may be signs of a serious allergic reaction. In such a case, contact a doctor immediately.
- need to receive a vaccine while on AFINITOR\*, seek your doctor’s advice first.

**Older people (age 65 years and over):** If you are aged 65 years or over you can take AFINITOR\* at the same dose as younger adults.

**Pregnancy and breast-feeding:** Ask your doctor or pharmacist for advice before taking any medicine. AFINITOR\* could harm an unborn baby or a breast-fed baby.

- AFINITOR\* is not recommended during pregnancy. If you are pregnant or think that you may be, tell your doctor who will discuss with you the potential risk of taking AFINITOR\* during pregnancy.

- Breast-feeding is not recommended during treatment with AFINITOR\*. Tell your doctor if you are breast-feeding.

**Women of child-bearing potential:** AFINITOR\* could harm an unborn baby or a breast-fed baby. You should use an effective contraceptive method during treatment with AFINITOR\* and for 8 weeks after treatment has stopped. If you think you may have become pregnant, ask your doctor for advice.

**Male fertility:** AFINITOR\* may affect your ability to father a child (fertility).

**Monitoring during your treatment with AFINITOR\*:** You will have regular blood tests during treatment. These will monitor the amount of blood cells (white blood cells, red blood cells and platelets) in your body to see if AFINITOR\* is having an unwanted effect on these cells. Blood tests will also be needed to monitor your kidney function (level of creatinine) and liver function (level of liver enzymes) and your blood sugar levels, because these can also be affected by AFINITOR\*.

## INTERACTIONS WITH THIS MEDICATION

**Tell your doctor or pharmacist before taking AFINITOR\*** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- drugs to treat infections (antifungals like ketoconazole, itraconazole; voriconazole and fluconazole; antibiotics like clarithromycin, telithromycin or erythromycin)
- drugs to treat tuberculosis, such as rifampicin or rifabutin
- St. John's wort (also known as *Hypericum perforatum*)
- corticosteroids like dexamethasone, prednisone, prednisolone
- drugs to stop seizures or fits (anti-epileptics like phenytoin, carbamazepine, phenobarbital)
- drugs to treat AIDS (HIV) like ritonavir, amprenavir, fosamprenavir, efavirenz, nevirapine
- drugs to treat heart conditions or high blood pressure (calcium channel blockers like verapamil and diltiazem)
- cyclosporine, a medicine to stop the body from rejecting organ transplants
- aprepitant, a medicine to prevent nausea and vomiting

**While you are taking AFINITOR\*** you should never start a new medicine without checking first with the doctor who prescribed AFINITOR\*. This includes prescribed medicines, over the counter medicines and herbal or alternative medicines.

## PROPER USE OF THIS MEDICATION

Your doctor will tell you exactly how many tablets of AFINITOR\* to take. Follow your doctor's instructions carefully.

### Usual dose:

The usual dose is 10 mg, to be taken by mouth once daily, at about the same time each day (preferably in the morning). AFINITOR\* should be taken on an empty stomach or after a light fat-free meal.

Swallow the tablets whole, with a glass of water. Do not chew or crush the tablets.

Continue taking AFINITOR\* as long as your doctor tells you.

### Overdose:

If you have taken too much AFINITOR\*, or if someone else accidentally takes your medicine, contact your doctor or a poison control centre for advice straight away. Show the pack of AFINITOR\*. Medical treatment may be necessary.

### Missed Dose:

If you forget to take AFINITOR\*, you may still take it up to 6 hours after the time you normally take it.

If you remember more than 6 hours after you normally take your AFINITOR\*, skip the dose for that day. The next day, take the tablet at your usual time. Do not take a double dose to make up for the one that you missed.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, AFINITOR\* can cause side effects. AFINITOR\* may also affect the result of some blood tests.

### **Very common and serious side effects:**

*These side effects may affect between 10 or more in every 100 patients.*

- **Lung or breathing problems** (pneumonitis, including interstitial disease or inflammation of the lung): **Tell your doctor straight away** if you experience new or worsening lung/breathing symptoms like cough, or shortness of breath, as this might have life-threatening consequences.
- **Infection: AFINITOR\* can make you more likely to get an infection (like pneumonia or a urinary tract infection).**

### **Very common side effects:**

*These side effects may affect 10 or more in every 100 patients.*

- Mouth ulcers
- Swelling of arms, hands, feet, ankles or other part of the body (signs of oedema)
- Stomach upsets like feeling sick (nausea), being sick (vomiting), diarrhoea
- Loss of appetite
- Feeling weak or tired
- Rash
- Dry skin

- Disturbed taste
- Itching (pruritus)
- Nose bleeds
- Fever
- Headache
- Low red blood cell count (anaemia)
- High cholesterol
- High triglycerides
- High blood sugar
- Arm and leg pains

If any of these affects you severely, **tell your doctor.**

**Common side effects:**

*These side effects may affect between 1 and 10 in every 100 patients.*

- Loss of weight
- Trouble sleeping (insomnia)
- Pain in abdomen, chest or jaw
- Kidney problems (kidney failure or high creatinine)
- Low lymphocyte, platelet or white blood cell count
- Dry mouth
- Dizziness
- Excess fluid around lung
- Breaking of finger/toenails or nail disorder
- Redness of skin, skin lesion or acne-like skin inflammation
- Haemorrhoids or bleeding
- Low blood phosphate or calcium
- Tingling sensation/feeling of numbness
- Rash/pain on palms or soles (hand foot syndrome)
- High blood pressure (hypertension)
- Chills
- Difficulty/pain in swallowing or throat pain
- Swelling of eyelids
- Runny nose
- High level of liver enzymes
- Heart problems, tachycardia (rapid heartbeat), heart failure (breathlessness, difficulty breathing when lying down, swelling of feet or legs)
- Worsening of diabetes (high blood sugar)
- Pink eye

If any of these affects you severely, **tell your doctor.**

**Uncommon side effects:**

*These side effects may affect between 1 and 10 in every 1,000 patients.*

- Onset of diabetes (high level of sugar in the blood)
- Abnormal wound healing

If any of these affects you severely, **tell your doctor.**

Hepatitis B reactivation has been observed in some patients receiving AFINITOR\*. Tell your doctor if you experience during

AFINITOR\* treatment symptoms of hepatitis B. The first symptoms may be non-specific, including fever, skin rash, joint pain and inflammation. Other symptoms may include fatigue, loss of appetite, nausea, jaundice (yellowing of the skin) and pain in the upper right abdomen. Pale stool or dark urine may also be signs of hepatitis.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Pain, discomfort or sores in the mouth		√	
Common	Lung or breathing problems (pneumonitis) (cough, shortness of breath)		√	
	Fever or chills or other signs of an infection as you might need urgent treatment		√	
	Increased frequency in urination		√	

*This is not a complete list of side effects. For any unexpected effects while taking AFINITOR\*, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Do not use after the expiry date shown on the box.

Store at room temperature (15 – 30 °C). Store in the original package to protect from light and moisture.

Keep out of the reach and sight of children and pets.

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor,  
Novartis Pharmaceuticals Canada Inc. at:  
1-800-363-8883

This leaflet was prepared by,  
Novartis Pharmaceuticals Canada Inc.  
385 Bouchard Blvd.  
Dorval, Quebec, H9S 1A9

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