NOVARTIS

AFINITOR

(everolimus)

5 and 10 mg Tablets

Patient Information Leaflet

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Access to the corresponding Professional Information To access the latest, approved Professional Information, scan the QR code with the camera from a smartphone or smart device. If you are unable to access the Professional Information via the QR code, kindly email your request for the Professional Information to: medinfo.za@novartis.com or call Novartis South Africa on (+27) 011 347 6600.	

SCHEDULING STATUS: S4

AFINITOR 5 mg (Tablets)

AFINITOR 10 mg (Tablets)

everolimus

Contains lactose

Read all of this leaflet carefully before you start taking AFINITOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- AFINITOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AFINITOR is and what it is used for

2. What you need to know before you take AFINITOR

3. How to take AFINITOR

4. Possible side effects

5. How to store AFINITOR

6. Contents of the pack and other information

1. What AFINITOR is and what it is used for

- AFINITOR is used to treat advanced kidney cancer (advanced renal cell carcinoma).
- In combination with another medicine called exemestane, AFINITOR is used to treat hormone receptor-positive advanced breast cancer which has become resistant to treatment.
- AFINITOR is used to treat advanced tumours called neuroendocrine tumours (NET) of the gastrointestinal system, lung or pancreas.
- AFINITOR is used to treat kidney tumour (angiomyolipoma) associated with a genetic disease called tuberous sclerosis complex (TSC), not requiring immediate surgery.

2. What you need to know before you take AFINITOR

Do not take AFINITOR:

- If you are hypersensitive (allergic) to everolimus, to related substances such as sirolimus or temsirolimus, or any of the other ingredients of AFINITOR
- If you are receiving live vaccines
- If you are pregnant or breast-feeding

Warnings and precautions:

- If you have any problems with your liver or have previously had a disease which may have affected your liver. It may be necessary to modify the dose of AFINITOR you receive.
- If you have diabetes (high level of sugar in your blood). AFINITOR may increase blood sugar levels and worsen diabetes mellitus. Tell your doctor if you experience any excessive thirst or increased frequency of urination.
- AFINITOR may increase the risk of problems with wound healing.
- If you have an infection. It may be necessary to treat your infection before starting AFINITOR.
- If you have high cholesterol. AFINITOR may elevate cholesterol and/or other blood fats.
- If you are about to have surgery, if you have had recent major surgery, or if you still have an unhealed wound following surgery. AFINITOR may impair wound healing.
- If you have previously had hepatitis B. This infection may be reactivated during treatment with AFINITOR.

- If you have non-infectious interstitial pneumonitis (inflammation of the lung).
- If you have *pneumocystis jirovecii (carinii) pneumonia* (PJP/PCP) (bacterial infection of the lung).
- If you have high blood pressure and are currently using an angiotensin-converting enzyme inhibitor (ACE), because this may increase the risk for angioedema (swelling of the airways or tongue).
- If you have received or are about to receive radiation treatment. Severe radiation reactions (such as shortness of breath, nausea, diarrhoea, skin rashes and soreness in mouth, gums and throat) have been observed in some patients receiving AFINITOR along with radiation therapy or shortly after radiation therapy.

AFINITOR may also:

- Weaken your immune system. Therefore, you may be at risk of getting an infection while you are taking AFINITOR.
- Impact your kidney function. Therefore, your doctor will monitor your kidney function while you are taking AFINITOR.
- Cause shortness of breath, cough and fever.

Tell your doctor if you experience these symptoms.

You will have regular blood tests during treatment. These will check 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 carried out to check your kidney function (level of creatinine) and liver function (level of transaminases) and your blood sugar and cholesterol levels. This is because these can also be affected by AFINITOR.

Children and adolescents

AFINITOR is not for children or adolescents (aged below 18 years).

Other medicines and AFINITOR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The following may increase the risk of side effects with AFINITOR:

Medicines to treat infections, such as

- ketoconazole, itraconazole, voriconazole or fluconazole, and other antifungal medicines used to treat fungal infections.
- clarithromycin, telithromycin or erythromycin (antibiotics used to treat bacterial infections).
- ritonavir, efavirenz, amprenavir, fosamprenavir or nevirapine (used to treat HIV infection/AIDS).
- verapamil or diltiazem used to treat heart conditions or high blood pressure.

- ciclosporin, a medicine used to stop the body from rejecting organ transplants.
- imatinib, used to inhibit the growth of abnormal cells.
- angiotensin-converting enzyme (ACE) inhibitors (such as ramipril) used to treat high blood pressure or some other heart problems.
- aprepitant, a medicine used to prevent nausea and vomiting.
- simvastatin and pravastatin, medicines to treat high cholesterol.
- midazolam, a medicine to treat acute seizures, or used as a sedative before or during surgery or a medical procedure.
- cannabidiol (uses amongst others include treatment of seizures).

The following may reduce the effectiveness of AFINITOR:

- rifampicin or rifabutin, used to treat tuberculosis (TB).
- St. John's Wort (*Hypericum perforatum*), an herbal product used to treat depression and other conditions.
- dexamethasone, prednisone or prednisolone (cortisones) used to treat a wide variety of conditions including inflammatory or immune problems.
- phenytoin, carbamazepine or phenobarbitone and other anti-epileptics used to stop seizures or fits.
- live vaccines such as intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, and TY21a typhoid vaccines.

These medicines should be avoided during your treatment with AFINITOR. If you are taking any of these, your doctor may switch you to a different medicine, or may change your dose of AFINITOR.

AFINITOR with food and drink and alcohol

You should take AFINITOR at the same time every day, either consistently with, or without, food. Avoid grapefruit and grapefruit juice while you are taking AFINITOR.

Pregnancy, Breastfeeding and Fertility:

You should not take AFINITOR during pregnancy.

If you are pregnant, or planning to become pregnant, or breastfeeding your baby while taking AFINITOR, please consult your doctor, pharmacist or other healthcare professional for advice.

AFINITOR could harm an unborn baby. Tell your doctor if you are pregnant or think that you may be pregnant. If you could potentially become pregnant, you should use highly effective contraception (like a barrier method plus a hormonal contraceptive or IUCD) 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 before taking any more AFINITOR.

Breastfeeding

AFINITOR could harm your baby. You should not breastfeed your baby during treatment with AFINITOR and for 2 weeks after the last dose of AFINITOR. Tell your doctor if you are breastfeeding.

Female fertility:

Absence of menstrual periods (amenorrhoea) has been observed in female patients receiving AFINITOR. AFINITOR may have an impact on female fertility. Talk to your doctor if you wish to have children.

Male fertility:

AFINITOR may affect male fertility. Talk to your doctor if you wish to father a child.

Driving and using machines

- AFINITOR can make you feel tired.
- Do not drive because AFINITOR could interfere with your ability to drive safely.
- Do not operate any tools or machines.

AFINITOR contains Lactose:

AFINITOR contains lactose (milk sugar). If you have been told by your doctor that you suffer from a hereditary disease called galactose intolerance (galactosaemia), Lapp lactase deficiency or glucose-galactose malabsorption, you should not use AFINITOR

3. How to take AFINITOR

Do not share medicines prescribed for you with any other person.

Always take AFINITOR exactly as your doctor has told you. Check with your doctor if you are not sure.

Follow your doctor's instructions carefully. Do not take more than your doctor has told you to.

Your doctor will tell you exactly how many tablets of AFINITOR to take, which will depend on your unique needs and situation.

If you have certain side effects from AFINITOR (e.g. breathing problems), your doctor might need to change the amount of AFINITOR you have to take.

Take AFINITOR once a day, every day, at about the same time each. It is important to take AFINITOR at about the same time every day, either with or without food, so that there is a steady amount in the bloodstream.

AFINITOR tablets must be taken by mouth.

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

Your doctor will tell you how long your treatment with AFINITOR will last.

If you have the impression that the effect of AFINITOR is too strong or too weak, tell your doctor or pharmacist.

If you take more AFINITOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AFINITOR

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for the forgotten tablets.

4. Possible side effects

AFINITOR can have side effects.

STOP taking AFINITOR and seek medical help immediately if you experience any of the following signs of an allergic reaction:

- difficulty breathing or swallowing;
- swelling of the face, lips, tongue or throat;
- severe itching of the skin, with a red rash or raised bumps.

If any of the following happens, stop taking AFINITOR and tell your doctor immediately or go to the casualty department at your nearest hospital.

Some side-effects can be serious. Serious side effects of AFINITOR include:

- Increased temperature or chills (signs of infection)
- Fatigue, loss of appetite, nausea, jaundice (yellowing of the skin), or pain in the upper right abdomen, pale stool or dark urine (may also be signs of Hepatitis B reactivation)
- Fever, coughing, difficulty breathing, wheezing, signs of inflammation of the lung (pneumonitis)
- Excessive thirst, high urine output, increased appetite with weight loss, tiredness (diabetes)
- Bleeding (haemorrhage), e.g. in the gut wall
- Severely decreased urine output, signs of kidney failure (renal failure)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs, signs of heart failure

- Swelling and/or pain in one of the legs, usually in the calf. Redness or warm skin in the affected area, signs of a blockage a blood vessel (vein) in the legs caused by blood clotting. Sudden onset of shortness of breath, chest pain or coughing up blood, potential signs of pulmonary embolism (a condition that occurs when one or more arteries in your lungs become blocked)
- Shortness of breath or rapid breath (signs of acute respiratory distress syndrome)
- Severely decreased quantity of urine, swelling in the legs, feeling confused and pain in the back, signs of sudden kidney failure (acute renal failure)
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of a serious allergic reaction- hypersensitivity).
- Swelling of the airways or tongue (angioedema).

If you experience any of these, tell your doctor straight away or go to the nearest hospital immediately.

Other side effects of AFINITOR include:

More frequent side effects:

- High blood sugar (hyperglycaemia);
- Loss of appetite;
- Disturbed taste (dysgeusia);
- Headache;
- Cough;

- Nose bleeds (epistaxis);
- Breathlessness (dyspnoea);
- Mouth ulcers;
- Upset stomach including feeling sick (nausea) or diarrhoea;
- Skin rash;
- Itching (pruritus);
- Feeling weak or tired;
- Tiredness, breathlessness, dizziness, pale skin, signs of low level of red blood cells (anaemia);
- Swelling of arms, hands, feet, ankles or other part of the body (signs of oedema);
- Weight loss;
- High level of lipids (fats) in the blood (hypercholesterolaemia or high levels of cholesterol in the blood);
- Thirst, low urine output, dark urine, dry flushed skin, irritability (signs of dehydration), protein in the urine (proteinuria);
- Trouble sleeping (insomnia);
- Headache, dizziness (sign of high blood pressure, also known as hypertension);
- Swelling of part or all of your arm (including fingers) or leg (including toes), feeling of heaviness, restricted movement, discomfort (possible symptoms of lymphoedema)
- Fever, sore throat, mouth ulcers due to infections (signs of low level of white blood cells, leukopenia, lymphopenia and/or neutropenia);

- Inflammation of the inner lining of the mouth, stomach and gut;
- Dry mouth;
- Heartburn (dyspepsia);
- Difficulty in swallowing (dysphagia);
- Abdominal pain;
- Excess amount of gas in the bowels (flatulence);
- Constipation;
- An inflammatory condition of the skin characterized by redness, itching, and oozing liquid-filled cysts which become scaly, crusted, or hardened (dermatitis acneiform)
- Acne;
- Rash and pain on the palms of your hands or soles of your feet (hand-foot syndrome);
- Reddening of the skin (erythema);
- Joint pain;
- Pain in the mouth;
- High level of lipids (fats) in the blood (hyperlipidaemia, raised triglycerides);
- Low levels of potassium in the blood (hypokalaemia);
- Low levels of phosphate in the blood (hypophosphataemia);
- High level of an enzyme called blood lactate dehydrogenase in the blood that gives information about the health of certain organs;
- Dry skin;

- Nail disorders;
- Abnormal results of liver blood tests (increased alanine and aspartate aminotransferase);
- Abnormal results of renal blood tests (increased creatinine);
- Urinary tract infection;
- Headache, pressure in the eyes, nose or cheek area, signs of inflammation of the sinuses and nasal passages;
- Middle ear infection;
- Skin inflammation (cellulitis);
- Sore throat and runny nose (nasopharyngitis, pharyngitis);
- Irritability;
- Menstruation disorders such as absence of periods (amenorrhoea), irregular or delayed periods, heavy periods (menorrhagia), or vaginal bleeds;
- Higher level of ovulation triggering hormone (blood luteinizing hormone increased).
- Impaired flow of the lymphatic system leading to swelling in the hands and/or feet (lymphedema).

Less frequent side effects:

- Tiredness, breathlessness, dizziness, pale skin /signs of low level of red blood cells (a type of anaemia called pure red cell aplasia);

- Weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells, also known as pancytopenia);
- Loss of sense of taste (ageusia);
- Coughing up blood (haemoptysis);
- Passing urine more often during daytime;
- Chest pain;
- Abnormal wound healing;
- Cough with phlegm, chest pain, fever, signs of inflammation of airways (bronchitis viral);
- Aggression;
- Higher level of female reproductive hormone (blood follicle stimulating hormone increased);
- Signs of serious infection also known as sepsis;
- Radiation reaction at the site of previous radiation therapy (e.g. skin redness or lung inflammation) (radiation recall syndrome).

Not all side effects reported for AFINITOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.SAHPRA.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AFINITOR.

5. How to store AFINITOR

Store at or below 30 °C. Protect from light and moisture. Store in original package. Store all medicines out of reach of children.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AFINITOR contains

The active substance is 5 mg or 10 mg everolimus, per tablet.

The other inactive ingredients are butylated hydroxytoluene (E321) (as antioxidant), magnesium stearate, lactose monohydrate, hypromellose, crospovidone, lactose anhydrous.

What AFINITOR looks like and contents of the pack

White to slightly yellow, elongated tablets with a bevelled edge and no score.

5 mg: The tablets are engraved with “5” on one side and “NVR” on the other.

10 mg: The tablets are engraved with “UHE” on one side and “NVR” on the other.

Holder of Certificate of Registration:

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AFINITOR 5 mg tablets: 30 September 2011

AFINITOR 10 mg tablets: 30 September 2011

Registration numbers

AFINITOR 5 mg tablets: 43/34/1010

AFINITOR 10 mg tablets: 43/34/1133

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AFINITOR 5 mg	14/26/0654	NS2	BOT 1502710	S2
AFINITOR 10 mg	14/26/0655	NS2	BOT 1502711	S2

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