

**Patient leaflet in accordance with the Pharmacists’ Regulations (Preparations) - 1986**

The medicine is dispensed with a doctor’s prescription only

## AFINITOR® 2.5 mg, 5 mg, 10 mg, tablets

Each tablet contains:  
Afinitor 2.5 mg:        everolimus 2.5 mg  
Afinitor 5 mg:         everolimus 5 mg  
Afinitor 10 mg:        everolimus 10 mg

Afinitor 2.5 mg, 5 mg, 10 mg, tablets

**Inactive ingredients and allergens:** See section 2 “Important information regarding some of the ingredients in the medicine” and section 6 “Further Information”.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about this medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

### 1. WHAT IS THIS MEDICINE INTENDED FOR?

**Afinitor Tablets 2.5, 5 and 10 mg are intended for:**

- Treatment of patients with brain tumor of the subependymal giant cell astrocytoma (SEGA) type associated with tuberous sclerosis complex (TSC) for whom surgery is not appropriate.
- Treatment of adult patients with a kidney tumor known as angiomyolipoma (AML) when the kidney tumor does not require immediate surgery. This type of tumor is connected with a genetic condition known as tuberous sclerosis complex.
- Treatment of patients with advanced neuroendocrine tumors of pancreatic origin that cannot be surgically removed, that are locally advanced or have metastasized.
- Treatment of advanced hormone receptor-positive and HER2-negative breast cancer, in conjunction with exemestane, in postmenopausal women without symptomatic metastatic disease spread to internal organs, after recurrence or progression of the disease following treatment with nonsteroidal aromatase inhibitors.
- Treatment of advanced kidney cancer (advanced renal cell carcinoma [RCC]), where other treatments that target vascular endothelial growth factor (VEGF-targeted therapy) have not helped stop the disease.
- Treatment of locally advanced, metastatic or unresectable, well-differentiated (1 or 2) non-functional neuroendocrine tumors of lung or gastrointestinal origin in adults with progressive disease.

**Therapeutic group:** anticancer medicine

Afinitor is a medicine whose active ingredient is called everolimus. It is an anti-cancer medicine which reduces the blood supply to cancer cells and can thus reduce the growth and spread of cancer cells. Afinitor can also reduce the size of kidney tumors called renal angiomyolipomas and SEGA brain tumor cells. The latter two tumors are caused by a genetic disorder called tuberous sclerosis complex (TSC).

### 2. BEFORE USING THE MEDICINE

Afinitor will only be prescribed to you by a doctor with experience treating cancer or by a specialist in the treatment of patients with tuberous sclerosis complex. Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet. If you have any questions about Afinitor or why it has been prescribed for you, consult your doctor.

<b>Do not use the medicine if:</b> <ul style="list-style-type: none"><li><b>You are allergic</b> (hypersensitive) to everolimus, to similar substances such as sirolimus, temsirolimus, or to any of the other ingredients that this the medicine contains and that are listed in section 6 “Further Information” in this leaflet. If you have had an allergic reaction before or if you think you are allergic, consult your doctor.</li></ul>
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**Special warnings regarding use of the medicine:**

**Before beginning treatment with Afinitor, tell your doctor if:**

- you have any problems with your liver or have previously had any diseases which may have affected your liver. If this is the case, your doctor may need to prescribe a different dose of Afinitor or stop treatment, temporarily or permanently.
- you have diabetes (high levels of sugar in the blood). Afinitor may cause an increase in blood sugar levels and worsen diabetes. This may lead to a need for medication such as insulin and/or oral anti-diabetic medicine. Tell your doctor if you experience increased thirst or increased frequency of urination.
- you need to receive a vaccine during treatment with Afinitor, as vaccination may be less effective. It is important to consult with the doctor regarding children suffering from brain tumors of the SEGA type on the subject of completing childhood series of vaccinations before treatment with Afinitor.
- you have a high level of cholesterol. Afinitor may elevate the level of cholesterol and/or other blood fats.
- you have recently had major surgery, or if you still have an unhealed wound following surgery. Afinitor may increase the risk of problems with wound healing.
- you have any infection. It may be necessary to treat your infection before starting treatment with Afinitor.
- you have previously had hepatitis B, because it may be reactivated during your treatment with Afinitor (see section 4: “Side effects”).
- you suffer or have suffered in the past from kidney problems.
- you have received or are about to receive radiation therapy (radiotherapy).

Afinitor may also:

- weaken your immune system. Therefore, you may be at risk of getting an infection while you are taking Afinitor. If you develop a fever or show other signs of an infection, consult your doctor. Some infections may be severe and may have fatal consequences in adults and children.
- impact your kidney function. Therefore, your doctor will monitor your kidney function while you are taking Afinitor.
- cause shortness of breath, cough, and fever (see also section 4 “Side effects”).
- cause mouth sores to develop (oral ulcerations). Your doctor might change or stop your Afinitor treatment. You might need treatment with a mouthwash, gel or other product. Some mouthwashes and gels can make ulcers worse, so do not try anything without checking with your doctor first. Your doctor might restart treatment with Afinitor at the same dose or at a lower dose.
- cause complications of radiation therapy. Severe complications of radiation therapy (such as shortness of breath, nausea, diarrhea, skin rashes and soreness in mouth, gums and throat), including fatal cases, have been observed in some patients who were taking everolimus at the same time as radiation therapy or who were taking everolimus shortly after they had radiation therapy. In addition, so called radiation recall syndrome comprising skin redness or lung inflammation at the site of previous radiation therapy has been reported in patients who had radiation therapy in the past. Tell your doctor if you are planning to have radiation therapy in the near future, or if you have had radiation therapy before.

**Inform your doctor immediately** if you experience these symptoms.

**Children and adolescents (below 18 years of age)**

Afinitor is intended for treating children and adolescents with a SEGA brain tumor associated with tuberous sclerosis complex (TSC) whose liver function is normal.

The safety and efficacy of Afinitor in children under one year old who have SEGA brain tumor associated with tuberous sclerosis complex (TSC) have not been established. No data are available.

Afinitor is not intended for use in children and adolescents for other approved indications.

**Tests and follow-up**

Before and during treatment with Afinitor you will have periodically blood tests which 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 carried out to check your kidney function (levels of creatinine, blood urea nitrogen or urinary protein), liver function (blood level of transaminases) and your blood sugar, fat, and cholesterol levels, because these can also be affected by Afinitor.

If you are taking Afinitor to treat a SEGA brain tumor associated with tuberous sclerosis complex (TSC), regular blood tests are also necessary to measure how much Afinitor is in your blood since this will help your doctor decide how much Afinitor you need to take.

**Drug interactions**

Afinitor may affect the way some other medicines work. If you are taking other medicines at the same time as Afinitor, your doctor might need to modify the dosage of Afinitor or the dosage of the other medicines.

**If you are taking, or have recently taken other medicines, including non-prescription medications and nutritional supplements, tell your doctor or pharmacist.** Particularly if you are taking:

The following medicines can increase the risk of side effects with Afinitor:

- anti-fungal medicines used to treat fungal infections, such as: ketoconazole, itraconazole, voriconazole, fluconazole.
- medicines used to treat types of bacterial infections, antibiotics such as: clarithromycin, telithromycin or erythromycin.
- medicines used to treat AIDS (HIV) such as: ritonavir.
- verapamil or diltiazem, which are medicines used to treat heart conditions or high blood pressure.
- a medicine used to regulate your heart beat: dronedarone.
- a medicine used to stop the body from rejecting organ transplants: cyclosporine.
- a medicine used to inhibit the growth of abnormal cells: imatinib.
- angiotensin-converting enzyme (ACE) inhibitors, medicines used to treat high blood pressure or other cardiovascular problems, such as ramipril.
- nefazodone, a medicine used to treat depression.

The following medicines can reduce the efficacy of Afinitor:

- a medicine used to treat tuberculosis: rifampicin.
- efavirenz or nevirapine, used to treat AIDS (HIV).
- St. John’s wort - a herbal medicine used to treat depression and other conditions (also known as *Hypericum Perforatum*).
- dexamethasone, a corticosteroid used to treat a wide variety of conditions including inflammatory or immune problems.
- medicines used to treat seizures or epileptic fits, anti-epileptics such as: phenytoin, carbamazepine or phenobarbital.

These medications should be avoided during your treatment with Afinitor. If you are taking any of these, your doctor might prescribe a different medicine or change your dosage of Afinitor.

For patients with TSC who are taking anti-seizure medications, a change in anti-seizure medication dosage (increase or decrease) may make a change in Afinitor dosage necessary, your doctor will decide this. If the dosage of your anti-seizure medicine changes, please inform your doctor.

**Use of the medicine and food**

This medicine can be taken with or without food, but be consistent and take it the same way every day.

Do not drink grapefruit juice or eat grapefruits during treatment with Afinitor. This may increase the amount of medicine in your blood, possibly to a harmful level.

**Pregnancy, breast-feeding, and fertility**

**Pregnancy**

Afinitor could harm your fetus and is therefore not recommended during pregnancy. Tell your doctor if you are pregnant or think that you may be pregnant. Your doctor will discuss with you whether you should take Afinitor during your pregnancy.

**Fertility**

Women of child-bearing potential should use a highly effective contraceptive method (such as condoms or the oral contraception) 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.

Afinitor may affect male and female fertility. If you are interested in becoming pregnant – consult the doctor.

Absence of menstrual periods (amenorrhaea) in women who previously had periods has been observed in some women receiving Afinitor.

**Breast-feeding**

Afinitor could harm your breast-fed baby. Do not breast-feed during treatment with Afinitor and for two weeks after the last dose of Afinitor. Tell your doctor if you are breast-feeding.

**Driving and using machines**

Exercise caution while driving or operating machinery during treatment with this medicine. Particularly if you feel unusually tired, since tiredness is a common to very common side effect of Afinitor.

Children should be cautioned against riding their bicycles or playing near the road, etc.

**Important information regarding some of the ingredients in the medicine**

Afinitor contains lactose (milk sugar). If you have been told by a doctor that you are sensitive to some sugars, consult the doctor before taking Afinitor.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor’s instructions.

Check with your doctor or pharmacist if you are uncertain the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

If you suffer from certain side effects (see section 4 “Side effects”) while you are taking Afinitor, your doctor may need to reduce your dosage of Afinitor, or to instruct you to stop treatment with Afinitor temporarily or permanently.

**Do not exceed the recommended dose.**

**Method of administration**

Take Afinitor by mouth, once a day, at about the same time every day, consistently either with or without food.

Swallow the tablet(s) whole with a glass of water.

There is no information about chewing, splitting, or crushing the tablet.

If you are taking Afinitor tablets to treat tuberous sclerosis complex with SEGA and you are unable to swallow the tablets, you can stir them into a glass of water:

- Put the required tablet(s) into a glass containing approximately 30 ml (2 tablespoons) of water.
- Gently stir the contents until the tablet(s) break apart (approximately 7 minutes) and drink immediately.
- Refill the glass with the same amount of water (approximately 30 ml), gently mix in any remaining medicine and drink the whole content to make sure that you get the full dose of Afinitor.
- If necessary, drink additional water to wash out any residues in your mouth.

**Instructions for caregivers regarding use and handling of Afinitor tablets**

Caregivers are advised to avoid contact with suspensions of Afinitor and wash hands thoroughly before and after preparing the suspension.

**If you have accidentally taken a higher dose**

If you have taken an overdose, or if a child or any other person has accidentally swallowed the medicine, refer immediately to the doctor or go to a hospital emergency room and bring the medicine package and the leaflet with you, so that the doctor will know what you have taken. Urgent medical treatment may be necessary.

**If you forget to take the medicine**

If you forget to take the medicine at the scheduled time, take your next dose as scheduled and consult your doctor. Do not take a double dose to make up for the one that you missed.

Be sure to adhere to the treatment as recommended by the doctor.

**If you stop taking this medicine**

Do not stop taking this medicine without consulting your doctor first.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

#### 4. SIDE EFFECTS

As with any medicine, use of Afinitor may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Stop** taking Afinitor and seek medical help immediately if you or your child experience any of the following signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat (signs of angioedema)
- severe itching of the skin, with a red rash or raised bumps

**Serious side effects of Afinitor include:**

**Serious side effects during the treatment of hormone receptor-positive advanced breast cancer, advanced kidney cancer, and advanced neuroendocrine tumors of pancreatic, gastrointestinal or lung origin include:**

**Very common side effects, effects occurring in more than one in ten users**

- increased body temperature, chills (signs of infection)
- fever, coughing, difficulty breathing, wheezing (signs of inflammation of the lung, inflammatory condition of lung tissue (pneumonitis))

**Common side effects, effects occurring in 1-10 in 100 users**

- excessive thirst, high urine output, increased appetite with weight loss, tiredness (signs of diabetes)
- bleeding (hemorrhage), for example in the gut wall
- severely decreased urine output (signs of kidney failure)

**Uncommon side effects, effects occurring in 1-10 in 1,000 users**

- fever, skin rash, joint pain and inflammation, tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stool, dark urine (may be signs of hepatitis B reactivation)
- 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 blockage of a blood vessel [vein] in the legs caused by a blood clot)
- 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)
- severely decreased urine output, swelling in the legs, feeling confused, pain in the back (signs of sudden kidney failure)
- rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of serious allergic reaction also known as hypersensitivity)

**Rare side effects, effects occurring in 1-10 in 10,000 users**

- shortness of breath or rapid breathing (signs of acute respiratory distress syndrome)

**If you experience any of these side effects, tell your doctor immediately, as they might have life-threatening consequences.**

**Serious side effects during the treatment of patients with a kidney tumor known as angiomyolipoma associated with tuberous sclerosis complex and of patients with a brain tumor of the subependymal giant cell astrocytoma type associated with tuberous sclerosis complex include:**

**Very common side effects, effects occurring in more than one in ten users**

- fever, coughing, difficulty breathing, wheezing (signs of inflammation of the lung due to infection [pneumonia])

**Common side effects, effects occurring in 1-10 in 100 users**

- swelling, feeling of heaviness or tightness, pain, limited mobility of body parts (potential sign of an abnormal build-up of fluid in soft tissue due to a blockage in the lymphatic system [lymphoedema])
- rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of serious allergic reaction also known as hypersensitivity)
- fever, coughing, difficulty breathing, wheezing (signs of inflammation of the lung, inflammatory condition of lung tissue [pneumonitis])

**Uncommon side effects, effects occurring in 1-10 in 1,000 users**

- rash of small fluid-filled blisters appearing on reddened skin (signs of viral infection that can be potentially severe, also known as herpes zoster)
- fever, chills, rapid breathing and heart rate, rash, and possibly confusion and disorientation (signs of serious infection also known as sepsis)

**If you experience any of these side effects, tell your doctor immediately, as they might have life-threatening consequences.**

**Additional side effects:**

**Other side effects during treatment of hormone receptor-positive advanced breast cancer, advanced kidney cancer or advanced neuroendocrine tumors of pancreatic, gastrointestinal or lung origin include:**

**Very common side effects, effects occurring in more than one in ten users**

high levels of sugar in the blood (hyperglycemia); loss of appetite; disturbed taste; headache; nose bleeds; cough; mouth ulcers; upset stomach including nausea or diarrhea; skin rash; itching; feeling weak or tired; tiredness, breathlessness, dizziness, pale skin, signs of low level of red blood cells (anemia); swelling of arms, hands, feet, ankles or other part of the body (signs of edema); weight loss; high level of lipids (fats) in the blood (hypercholesterolemia).

**Common side effects, effects occurring in 1-10 in 100 users**

spontaneous bleeding or bruising (signs of low level of platelets [thrombocytopenia]); breathlessness (dyspnea); thirst, low urine output, dark urine, dry flushed skin, irritability (signs of dehydration); trouble sleeping (insomnia); headache, dizziness (signs of high blood pressure [hypertension]); swelling of part or all of your arm (including fingers) or legs (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]); fever; inflammation of the inner lining of the mouth, stomach, gut; dry mouth; heartburn (dyspepsia); vomiting; difficulty in swallowing (dysphagia); abdominal pain; acne; rash and pain on the palms of your hands or soles of your feet (hand-foot syndrome); skin reddening (erythema); joint pain; pain in the mouth; menstruation disorders such as irregular periods; high level of lipids (fats) in the blood (hyperlipidemia, raised triglycerides); low level of potassium in the blood (hypokalemia); low level of phosphate in the blood (hypophosphatemia); low level of calcium in the blood (hypocalcemia); dry skin, skin exfoliation, skin lesions; nail disorders, breaking of your nails; mild hair loss; abnormal results of liver blood tests (increased alanine and aspartate aminotransferase); abnormal results of renal blood tests (increased creatinine); swelling of the eyelid; protein in the urine.

**Uncommon side effects, effects occurring in 1-10 in 1,000 users**

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 [pancytopenia]); loss of sense of taste (ageusia); coughing up blood (hemoptysis); menstruation disorders such as absence of periods (amenorrhea); passing urine more often during daytime; chest pain; abnormal wound healing; hot flushes; discharge from the eye with itching and redness, pink or red eye (conjunctivitis).

**Rare side effects, effects occurring in 1-10 in 10,000 users**
tiredness, breathlessness, dizziness, pale skin (signs of low levels of red blood cells possibly due to a type of anemia called pure red cell aplasia); swelling of the face, around the eyes, mouth, and inside the mouth and/or throat, as well as the tongue and difficulty breathing or swallowing (also known as angioedema) may be signs of an allergic reaction.

**Side effects whose frequency is not known (frequency has not been established yet)**

Reaction at the site of previous radiation therapy, e.g. skin redness or lung inflammation (so called radiation recall syndrome); worsening of radiation treatment side effects.

**If these side effects get severe, please consult your doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear after a few days of treatment interruption.**

**Other side effects during the treatment of patients with a kidney tumor known as angiomyolipoma associated with tuberous sclerosis complex and of patients with a brain tumor of the subependymal giant cell astrocytoma type associated with tuberous sclerosis complex include:**

**Very common side effects, effects occurring in more than one in ten users**

upper respiratory tract infection; sore throat and runny nose (nasopharyngitis); headache, pressure in the eyes, nose or cheek area (signs of inflammation of the sinuses and nasal passages [sinusitis]); urinary tract infection; high level of lipids (fats) in the blood (hypercholesterolemia); decreased appetite; headache; cough; mouth ulcers; diarrhea; vomiting; acne; skin rash; feeling tired; fever; menstruation disorders such as absence of periods (amenorrhœa) or irregular periods; sore throat (pharyngitis); headache, dizziness, signs of high blood pressure [hypertension].

**Common side effects, effects occurring in 1-10 in 100 users**

middle ear infection; swollen, bleeding gums (signs of gum inflammation [gingivitis]); skin inflammation (cellulitis); high level of lipids (fats) in the blood (hyperlipidemia, raised triglycerides); low level of phosphate in the blood (hypophosphatemia); high level of sugar in the blood (hyperglycemia); tiredness, breathlessness, dizziness, pale skin (signs of low level of red blood cells [anemia]); fever, sore throat or mouth ulcers due to infections (signs of low level of white blood cells [leukopenia, lymphopenia, neutropenia]); spontaneous bleeding or bruising (signs of low level of platelets [thrombocytopenia]); mouth pain; nose bleeds; stomach upset such as nausea; abdominal pain; severe pain in the lower abdomen and pelvic area that may be sharp, with menstrual irregularities (ovarian cyst); excess amount of gas in the bowels (flatulence); constipation; abdominal pain, nausea, vomiting, diarrhea, swelling of the abdomen (signs of inflammation of the stomach lining also called gastritis or gastroenteritis viral); dry skin, itching; an inflammatory condition of the skin characterized by redness, itching, and oozing liquid-filled cysts which become crusted, scaly, or hardened (dermatitis acneiform); hair loss; protein in the urine; menstruation disorders such as heavy periods (menorrhagia) or vaginal bleeding; trouble sleeping (insomnia); irritability; aggression; high level of an enzyme in the blood called lactate dehydrogenase that gives information about the health of certain organs; higher level of ovulation triggering hormone in the blood (increased luteinizing hormone [LH]); weight loss.

**Uncommon side effects, effects occurring in 1-10 in 1,000 users**

muscle spasm, fever, red-brown urine, these are possibly signs of a muscle disorder (rhabdomyolysis); cough with phlegm, chest pain, fever (signs of inflammation of airways also known as bronchitis viral); disturbed taste; menstruation disorders such as delayed periods; higher blood level of female reproductive hormone (increase in follicle stimulating hormone [FSH]).

**Side effects whose frequency is not known (frequency has not been established yet)**

Reaction at the site of previous radiation therapy, e.g. skin redness or lung inflammation (so called radiation recall syndrome); worsening of radiation treatment side effects.

**If these side effects get severe, please consult your doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear after a few days of treatment interruption.**

**If a side effect occurs, if any side effect worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Hepatitis B reactivation has been observed in some patients taking Afinitor. Tell your doctor if you experience symptoms of hepatitis B during treatment with Afinitor. The first symptoms may include 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 stools or dark urine may also be signs of hepatitis.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

#### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package to protect from light and moisture.
- Open the blister (tray) pack immediately before taking Afinitor tablets.
- Do not use if you notice that the package is damaged.

Do not throw away any medicines via household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

#### 6. FURTHER INFORMATION

**In addition to the active ingredient this medicine also contains:**

lactose anhydrous, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, and butylated hydroxytoluene.

Each Afinitor 2.5 mg tablet contains 74 mg lactose.

Each Afinitor 5 mg tablet contains 149 mg lactose.

Each Afinitor 10 mg tablet contains 297 mg lactose.

**What does the medicine look like and what are the contents of the package:**

The tablets are white to slightly yellowish, elongated with beveled edges and no score line.

Afinitor 2.5 mg: The tablets are smooth, embossed with “LCL” on one side and “NVR” on the other.

Afinitor 5 mg: The tablets are smooth, embossed with “5” on one side and “NVR” on the other.

Afinitor 10 mg: The tablets are smooth, embossed with “UHE” on one side and “NVR” on the other.

Each package contains 30 tablets.

**Name and address of registration holder and importer:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

**Registration number of the medicine in the Ministry of Health’s National Drug Registry:**

Afinitor 2.5 mg: 146 82 33388

Afinitor 5 mg: 142 86 32045

Afinitor 10 mg: 142 87 32046

Revised in January 2022 according to MOH guidelines.