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

The medicine is dispensed with a doctor's prescription only

Everolimus Taro 2.5 mg, Tablets	**Everolimus Taro 5 mg, Tablets**	**Everolimus Taro 10 mg Tablets**
Active ingredient: Each tablet contains: everolimus 2.5 mg	**Active ingredient:** Each tablet contains: everolimus 5 mg	**Active ingredient:** Each tablet contains: everolimus 10 mg

Inactive ingredients and allergens: See section 2 under 'Important information regarding some of this medicine's ingredients' and section 6 'Further Information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Everolimus Taro 2.5, 5 and 10 mg tablets are intended for:

- Treatment of patients with a subependymal giant cell astrocytoma (SEGA), a type of brain tumor 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 associated with a genetic condition known as tuberous sclerosis complex.
- 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 your 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.

Everolimus Taro is a medicine whose active ingredient is called everolimus. It is an anti-tumor medicine which reduces the blood supply to cancer cells and can thus reduce the growth and spread of cancer cells.

Everolimus Taro can also reduce the size of kidney tumors called renal angiomyolipomas and SEGA brain tumors.

The latter two tumors are caused by a genetic disorder called tuberous sclerosis complex (TSC).

2. BEFORE USING THE MEDICINE

Everolimus Taro 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 Everolimus Taro or why this medicine has been prescribed for you, consult your doctor.

Do not use the medicine if:

- You are sensitive (allergic) to everolimus, to similar substances such as sirolimus, temsirolimus, or to any of the other ingredients that the medicine contains and that are listed in section 6 'Further Information' in this leaflet.
  If you have experienced an allergic reaction before or if you think you are allergic, consult your doctor.
- You are breastfeeding.

Special warnings about using this medicine:
Before beginning treatment with Everolimus Taro, 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 you a different dose of Everolimus Taro or stop treatment, temporarily or permanently.
- you have diabetes (high levels of sugar in the blood). Everolimus Taro may cause an increase in blood sugar levels and worsen diabetes. This may lead to a need for medication therapy such as insulin and/or oral treatment with an 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 Everolimus Taro, as vaccination may be less effective. It is important to consult with the doctor regarding children suffering from SEGA brain tumors on the subject of completing childhood series of vaccinations before treatment with Everolimus Taro.
- you have a high level of cholesterol. Everolimus Taro 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. Everolimus Taro 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 Everolimus Taro.
- you have previously had hepatitis B, because it may be reactivated during your treatment with Everolimus Taro (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)

Everolimus Taro may also:

- weaken your immune system. Therefore, you may be at risk of infection while you are taking Everolimus Taro. If you develop a fever or 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 during treatment with Everolimus Taro.
- 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 Everolimus Taro 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 Everolimus Taro at the same dose or at a lower dose.
- cause complications of radiotherapy. Severe complications of radiotherapy (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 radiotherapy or who were taking everolimus shortly after they had radiotherapy. In addition, so-called radiation recall syndrome, comprising skin redness or lung inflammation at the site of previous radiotherapy has

been reported in patients who had radiotherapy in the past.
Tell your doctor if you are planning to have radiotherapy 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)
Everolimus Taro 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 Everolimus Taro in children under one year old who have a SEGA brain tumor associated with tuberous sclerosis complex (TSC) have not been established. There is no data.
Everolimus Taro is not intended for use in children and adolescents for other approved indications.

Tests and follow-up
Before and during treatment with Everolimus Taro you will need to have routine blood tests that will monitor the amount of blood cells (white blood cells, red blood cells and platelets) in your body, to see if Everolimus Taro is having an undesirable effect on these cells. Blood tests will also be carried out to monitor your kidney function (levels of creatinine, blood urea nitrogen or urinary protein), liver function (blood level of transaminases) and your blood sugar, lipid, and cholesterol levels, because these may also be affected by Everolimus Taro.

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

Drug interactions
Everolimus Taro may affect the way other medicines work. If you are taking other medicines at the same time as Everolimus Taro, your doctor might need to modify the dosage of Everolimus Taro or the dosage of the other medicines.
If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

The following medicines can increase the risk of side effects with Everolimus Taro:
- 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, medicines used to treat heart conditions or high blood pressure.
- a medicine used to regulate your heart beat: dronedarone.
- a medicine used to prevent the body from rejecting 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.
- cannabidiol (uses amongst others include treatment of seizures).

The following medicines can reduce the efficacy of Everolimus Taro:
- 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 Everolimus Taro. If you are taking any of these, your doctor might prescribe a different medicine or change your dosage of Everolimus Taro.

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 Everolimus Taro dosage necessary, your doctor will decide this. If the dosage of your anti-seizure medicine changes, please inform your doctor.

Using this 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 Everolimus Taro. This may increase the amount of medicine in your blood, possibly to a harmful level.

Pregnancy, breastfeeding, and fertility
Pregnancy
Everolimus Taro could harm your fetus and is 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 Everolimus Taro during your pregnancy.

Breastfeeding
Everolimus Taro could harm your breastfed baby. Do not breastfeed during treatment and for two weeks after the last dose of Everolimus Taro. Tell your doctor if you are breastfeeding.

Fertility
Women of child-bearing potential should use a highly effective contraceptive method (such as condoms or oral contraception) during treatment with Everolimus Taro and for 8 weeks after treatment has stopped. If you think you are pregnant, ask your doctor for advice **before** taking any more Everolimus Taro.

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

Absence of menstrual periods (amenorrhea) in women who previously had periods has been observed in some women who have taken Everolimus Taro.

Driving and using machines
Exercise extra caution while driving or using machinery while using this medicine, particularly if you feel unusually tired, since tiredness is a common to very common side effect of Everolimus Taro.
Caution children against riding a bicycle, playing near a road, etc.

Important information regarding some of this medicine's ingredients
Everolimus Taro contains lactose (milk sugar). If you have been told by a doctor that you are sensitive to some sugars, consult the doctor before taking Everolimus Taro.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor’s instructions.
Check with your doctor or pharmacist if you are not sure about your dosage and about how to take this 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') during treatment with Everolimus Taro, your doctor may need to reduce your dosage of Everolimus Taro you need to take or to instruct you to stop treatment with Everolimus Taro temporarily or permanently.

Do not exceed the recommended dose.

Method of administration
Take Everolimus Taro 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 Everolimus Taro tablets to treat tuberous sclerosis complex with SEGA and you are unable to swallow the tablets, you can stir them in a glass of water:
- Put the required tablet(s) into a glass of water (approximately 30 ml (2 tablespoons)).
- 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 the rest of the content and drink the whole content to make sure that you get the full dose of Everolimus Taro.
- If necessary, drink additional water to wash out any residues in your mouth.

Instructions for caregivers regarding use and handling of Everolimus Taro tablets
Caregivers are advised to avoid contact with suspensions of Everolimus Taro. 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 at the regular time 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.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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. <u>SIDE EFFECTS</u>

Like with all medicines, using Everolimus Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking Everolimus Taro 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

Severe side effects of Everolimus Taro include:

Severe side effects during the treatment of <u>hormone receptor-positive advanced breast cancer, advanced kidney cancer, and advanced neuroendocrine tumors of gastrointestinal or lung origin (with the exception of neuroendocrine pancreatic tumors) include:</u>

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 severe 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.

Severe side effects <u>during the treatment of patients with a kidney tumor called angiomyolipoma associated with tuberous sclerosis complex and of patients with a subependymal giant cell astrocytoma brain tumor associated with tuberous sclerosis complex include:</u>

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 severe 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 severe infection also called 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 <u>hormone receptor-positive advanced breast cancer, advanced kidney cancer or advanced neuroendocrine tumors of gastrointestinal or lung origin (with the exception of neuroendocrine pancreatic tumors) include:</u>

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, pallor, signs of low level of red blood cells (anemia); swelling of arms, hands, feet, ankles or other area of the body (signs of edema); weight loss; high level of lipids 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, lower 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 the 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]); infection 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 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 flashes; 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, pallor (signs of low level 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 of unknown frequency (the frequency of these effects has not been established yet)
Reaction at the site of previous radiotherapy, e.g. skin redness or lung inflammation (so-called radiation recall syndrome).

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

Other side effects during the treatment of patients with a kidney tumor called angiomyolipoma associated with tuberous sclerosis complex and of patients with a subependymal giant cell astrocytoma brain tumor 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 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 (amenorrhea) 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 infection (gingivitis)); skin inflammation (cellulitis); high level of lipids 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, pallor (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 viral gastroenteritis); 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 provides 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 called viral bronchitis); taste disorder; menstruation disorders such as delayed periods; higher blood level of female reproductive hormone (increase in follicle stimulating hormone, FSH).

Side effects of unknown frequency (the frequency of these effects has not been established yet)
Reaction at the site of previous radiotherapy, e.g. skin redness or lung inflammation (so-called radiation recall syndrome), worsening of radiotherapy side effects.

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

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

Hepatitis B reactivation has been diagnosed in some patients taking Everolimus Taro. Tell your doctor if you experience symptoms of hepatitis B during treatment with Everolimus Taro. 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.

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. 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.

Storage conditions:
- Store below 25°C.
- Store in the original package to protect from light and moisture.
- Open the blister (tray) pack immediately before taking Everolimus Taro 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 throw away 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, crospovidone (type A), hypromellose (2910), lactose monohydrate, magnesium stearate, and butylhydroxytoluene

What the medicine looks like and contents of the pack:
The tablets are white to cream colored, oval, biconvex.
Everolimus Taro 2.5 mg: The tablets are engraved with "2.5" on one side and "E9VS" on the other.
Everolimus Taro 5 mg: The tablets are engraved with "E9VS 5" on one side.
Everolimus Taro 10 mg: The tablets are engraved with "E9VA 10" on one side.

Each package contains 10, 30 or 90 tablets.

Registration Holder and Importer and its address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Manufacturer's name and address: Synthon Chile Ltd., El Castano No 145, Valle Grande, Lampa, Santiago, Chile

Revised in December 2022 according to MOH guidelines.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Everolimus Taro 2.5 mg: **167-99-35839-00**
Everolimus Taro 5 mg: **168-01-35840-00**
Everolimus Taro 10 mg: **168-02-35841-00**