PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Everolimus Teva 2.5 mg
Everolimus Teva 5 mg
Everolimus Teva 7.5 mg
Everolimus Teva 10 mg
Tablets

Composition:

Each tablet of Everolimus Teva 2.5 mg contains: Everolimus 2.5 mg

Each tablet of Everolimus Teva 5 mg contains: Everolimus 5 mg

Each tablet of Everolimus Teva 7.5 mg contains: Everolimus 7.5 mg

Each tablet of Everolimus Teva 10 mg contains: Everolimus 10 mg

For information about inactive ingredients and allergens in the preparation see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Everolimus Teva is intended for:

- Treatment of patients with a 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 have advanced locally or metastatic disease.
- Treatment of hormone receptor-positive and HER2-negative advanced 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 treatment with Vascular Endothelial Growth Factor (VEGF) targeted therapy has not helped in stopping the disease.
- Treatment of nonfunctional, well-differentiated (Grade 1 or Grade 2) neuroendocrine tumors of gastrointestinal or lung origin, that are locally advanced or have metastasized or that cannot be surgically removed, in adults with a progressive disease.

Therapeutic class: anticancer medicine.

Everolimus Teva is a medicine whose active ingredient is called everolimus. An anticancer medicine that reduces the blood supply to the cancer cells and thus can reduce the growth and spread of the cancer cells.

Everolimus Teva can also reduce the size of kidney tumor cells called angiomyolipoma and SEGA type brain tumor cells.

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

2. BEFORE USING THE MEDICINE

Everolimus Teva will only be prescribed to you by a specialist with experience treating cancer or by a specialist in the treatment of patients with tuberous sclerosis complex.

Make sure to follow all the doctor's instructions. They may differ from the general information contained in this leaflet.

If you have any questions about Everolimus Teva or if you need an explanation as to why this medicine was prescribed for you, consult the doctor.

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, to similar agents such as sirolimus, temsirolimus, or to any of the other ingredients this medicine contains (see section 6 – "Additional information").If you have experienced an allergic reaction in the past or if you think you are allergic, consult the doctor.

Special warnings regarding the use of the medicine:

Before treatment with Everolimus Teva, inform the doctor if:

- You have any problems with your liver or if you have had any diseases which may have affected your liver. In this case, the doctor may need to prescribe a different dose of Everolimus Teva for you or you may need to stop the treatment, temporarily or permanently.
- You have diabetes (high levels of sugar in the blood). Everolimus Teva may cause an increase in blood sugar levels and worsen diabetes. This may lead to a need for medicinal treatment such as insulin and/or oral treatment with an anti-diabetic agent. Tell the doctor if you experience excessive thirst or increased frequency of urination.
- You need to receive a vaccine during treatment with Everolimus Teva, as the vaccination may be less effective. It is important to speak to the doctor about children suffering from SEGA type brain tumor, about the completion of the childhood vaccination program before treatment with Everolimus Teva.
- You have a high level of cholesterol. Everolimus Teva 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 Teva may increase the risk of problems with wound healing.
- You have any infection. It may be necessary to treat the infection before starting treatment with Everolimus Teva.
- You have previously had a type B viral infection of the liver (hepatitis B), because the disease may be reactivated during treatment with Everolimus Teva (see section 4 - "Side effects").
- You are suffering or have suffered in the past from kidney problems.
- You have undergone or are about to undergo radiotherapy.

In addition, Everolimus Teva may:

- Weaken your immune system. Therefore, you may be at risk of infection during treatment with Everolimus Teva. If you develop a fever or other signs of an infection, consult the doctor. Some infections may be severe and may have fatal consequences in adults and children.
- Affect kidney function. Therefore, the doctor will monitor your kidney function during treatment with Everolimus Teva.
- Cause shortness of breath, cough and fever (see also section 4 - "Side effects").
- Cause the development of sores in the mouth (mouth ulcers). The doctor may change or stop the treatment with Everolimus Teva. You may need treatment with a mouthwash, gel or other preparation. Some mouthwashes and gels may aggravate ulcers, so do not try anything without checking with the doctor first. The doctor may restart the treatment with Everolimus Teva at the same dose or at a lower dose.
- Cause complications of radiotherapy. Severe complications of radiotherapy (e.g., shortness of breath, nausea, diarrhea, skin rashes and sore mouth, gums and throat), including fatal cases, have been observed in some patients who have taken Everolimus Teva alongside radiotherapy, or who have taken Everolimus Teva shortly after undergoing radiotherapy. In addition, an effect called 'radiation recall syndrome' has been reported, which includes skin redness or pneumonitis in an area previously treated by radiotherapy, in patients who have previously undergone radiotherapy. Inform the doctor if you are planning to undergo radiotherapy soon, or if you have undergone radiotherapy in the past.

Inform the doctor immediately if you experience these symptoms.

Children and adolescents (under the age of 18):

Everolimus Teva is intended for the treatment of children and adolescents with a SEGA type brain tumor associated with tuberous sclerosis complex (TSC) whose liver function is normal.

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

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

Tests and follow-up:

Before and during treatment with Everolimus Teva you will undergo routine blood tests, which will monitor the amount of blood cells in your body (white blood cells, red blood cells and platelets), to see if Everolimus Teva has an unwanted effect on these cells. Blood tests will also be performed to monitor kidney function (creatinine levels, blood urea nitrogen concentration (urea) or protein in the urine), liver function (blood transaminases levels) and blood sugar levels, fats and cholesterol levels, as these may all be affected by Everolimus Teva.

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

Drug interactions:

Everolimus Teva may affect the way some other medicines work. If you are taking other medicines concomitantly with Everolimus Teva, the doctor may need to change the dosage of Everolimus Teva or the dosage of the other medicines.

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:

The following medicines may increase the risk of side effects when used with Everolimus Teva:

- Antifungal 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 problems or high blood pressure.
- A medicine used to regulate heart rate: dronedarone.
- A medicine used to prevent 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.
- Cannabidiol (used for treatment of seizures, among other things).

The following medicines can reduce the efficacy of Everolimus Teva:

- A medicine used to treat tuberculosis: rifampicin.
- Efavirenz or nevirapine - used to treat AIDS (HIV).
- St. John's Wort - an 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 system problems.
- Medicines used to treat seizures or epileptic seizures, antiepileptic medications such as: phenytoin, carbamazepine or phenobarbital.

These medicines should be avoided during treatment with Everolimus Teva. If you are taking one of these medicines, the doctor may prescribe a different medicine for you or change the dosage of Everolimus Teva.

In patients with TSC who are taking anti-seizure medicines, a change in the dosage of the anti-seizure medicine (increase or decrease) may require a change in the dosage of Everolimus Teva, the doctor will decide this. If the dosage of your anti-seizure medicine changes, please inform the doctor.

Use of the medicine and food:

The medicine can be taken with or without food, but do so consistently in the same way every day. Do not drink grapefruit juice or eat grapefruit during treatment with Everolimus Teva. It may increase the amount of medicine in your blood, possibly to a harmful level.

Pregnancy, breastfeeding and fertility:

Pregnancy:

Everolimus Teva may harm your fetus and is not recommended during pregnancy. Tell the doctor if you are pregnant or think that you may be pregnant. The doctor will discuss with you whether you should take Everolimus Teva during your pregnancy.

Fertility:

Women of childbearing age should use highly effective contraceptive methods (such as: condoms or oral contraceptives) during treatment with Everolimus Teva and for 8 weeks after ending treatment. If you think you may be pregnant, consult the doctor **before** taking any more Everolimus Teva.

Everolimus Teva may have an effect on 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.

Breastfeeding:

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

Driving and operating machinery:

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 Everolimus Teva.

Children should be cautioned against riding a bicycle or playing near a road etc.

Important information about some ingredients of the medicine:

Everolimus Teva contains **lactose**. If you have been told by a doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

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

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

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

If you suffer from certain side effects (see section 4 - "Side effects") during treatment with Everolimus Teva, the doctor may reduce your dosage of Everolimus Teva, or instruct you to stop treatment with Everolimus Teva for a short while or permanently.

Do not exceed the recommended dose.

How to take the medicine:

Everolimus Teva should be taken by mouth once a day, every day at about the same time, consistently with or without food.

The tablets should be swallowed whole with a glass of water.

Do not chew, crush or halve the tablets.

If you accidentally took a higher dosage:

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 forgot to take the medicine:

If you forgot to take the medicine at the scheduled time, take the next dose as scheduled and consult the doctor. Do not take a double dose to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine:

Do not stop treatment with the medicine without consulting the doctor.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Everolimus Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop taking Everolimus Teva 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 with raised bumps.

Serious side effects of Everolimus Teva include:

Serious side effects during the treatment of hormone receptor-positive advanced breast cancer, advanced kidney cancer, and advanced neuroendocrine tumors originating in the pancreas, gastrointestinal tract or lungs include:

Very common side effects - side effects that occur in more than 1 out of 10 users:

- Increased body temperature, chills (signs of infection).
- Fever, cough, breathing difficulties, wheezing (signs of inflammation in the lung, inflammatory process of the lung tissue (pneumonitis)).

Common side effects - side effects that occur in 1-10 out of 100 users:

- Excessive thirst, increased urination, increased appetite with weight loss, tiredness (signs of diabetes).
- Bleeding (hemorrhage), for example in the intestinal wall.
- Severe decreased urination (signs of renal failure - kidney failure).

Uncommon side effects - side effects that occur in 1-10 out of 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 stools, dark urine (may be signs of hepatitis B reactivation).
- Shortness of breath, difficulty breathing while lying down, swelling in 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 due to a blood clot).
- Sudden onset of shortness of breath, chest pain or bloody cough (may be signs of pulmonary embolism, a condition that occurs when one or more arteries of the lungs become blocked).
- Severe decreased urination, swelling in the legs, feeling confused, back pain (signs of sudden kidney failure).
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of a severe allergic reaction, also called hypersensitivity).

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

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

If you experience one of these side effects, contact the doctor immediately as the results may be life-threatening.

Serious side effects during treatment of patients with a kidney tumor called 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 - side effects that occur in more than 1 out of 10 users:

Fever, cough, breathing difficulties, wheezing (signs of inflammation in the lung as a result of an infection (pneumonia)).

Common side effects - side effects that occur in 1-10 out of 100 users:

- Swelling, feeling of heaviness or tightness, pain, limited mobility of body parts (possible signs of abnormal fluid accumulation in soft tissue due to a blockage in the lymphatic system (lymphedema)).
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of a severe allergic reaction, also called hypersensitivity).
- Fever, cough, breathing difficulties, wheezing (signs of inflammation in the lung, inflammatory process of the lung tissue (pneumonitis)).

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Rash of small fluid-filled blisters that appear on reddish skin (signs of a potentially serious viral infection, also called herpes zoster).
- Fever, chills, rapid breathing and heart rate, rash and possible confusion and disorientation (signs of a serious infection, also called sepsis).

If you experience one of these side effects, contact the doctor immediately as the results may be life-threatening.

Additional side effects:

Other additional side effects during treatment of hormone receptor-positive advanced breast cancer, advanced kidney cancer or advanced neuroendocrine tumors originating in the pancreas, gastrointestinal tract or lungs include:

Very common side effects - side effects that occur in more than 1 out of 10 users:

High levels of sugar in the blood (hyperglycemia); loss of appetite, disturbed taste; headache; nose bleeding; cough; mouth ulcers; abdominal discomfort including nausea or diarrhea; skin rash; itching; a feeling of weakness or fatigue; tiredness, shortness of breath, dizziness, pallor (signs of low level of red blood cells (anemia)); swelling of the arms, hands, feet, ankles or other area of the body (signs of edema); weight loss, high level of fats in the blood (excess cholesterol in the blood).

Common side effects - side effects that occur in 1-10 out of 100 users:

Spontaneous bleeding or bruising (signs of low platelet count (thrombocytopenia)); shortness of breath (dyspnea); thirst, decreased urination, dark urine, flushed and dry skin, restlessness (signs of dehydration); sleep problems (insomnia); headache, dizziness (signs of high blood pressure - hypertension); swelling of part of or the entire arm (including the fingers) or the legs (including the toes), feeling of heaviness, limited movement, discomfort (possible symptoms of lymphedema); fever, sore throat, mouth ulcers due to infections (signs of low level of white blood cells (leukopenia, lymphopenia and/or neutropenia)); fever; infection in the inner wall of the mouth, stomach, intestines; dry mouth; heartburn (indigestion); vomiting; difficulty swallowing (dysphagia); abdominal pain; acne; rash and pain on the palm of the hands or soles of the feet (hand-foot syndrome); reddening of the skin (erythema); joint pain; pain in the mouth; menstrual disorders such as irregular periods; high level of 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, peeling skin, skin lesions; nail disorders, breaking 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 - side effects that occur in 1-10 out of 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); menstrual disorders such as absence of menstrual periods (amenorrhea); urinating more frequently during the day; chest pains; abnormal wound healing; hot flashes; discharge from the eye accompanied by itching and redness, pink or red eye (conjunctivitis).

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

Tiredness, shortness of breath, dizziness, pallor (signs of low level of red blood cells, possibly as a result of a type of anemia called pure red cell aplasia); swelling of the face, around the eyes, the mouth, and inside the mouth and/or the throat, as well as swelling of the tongue and difficulty breathing or swallowing (also known as angioedema), may be signs of an allergic reaction.

Side effects with unknown frequency (effects whose frequency has not yet been determined)

A reaction in an area previously treated by radiotherapy, such as skin redness or pneumonitis (called 'radiation recall syndrome'); worsening of radiotherapy side effects.

If these side effects worsen, please contact the doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear several days after stopping treatment.

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

Very common side effects - side effects that occur in more than 1 out of 10 users:

Inflammation of the upper respiratory tract; 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 fats in the blood (excess cholesterol in the blood); decreased appetite; headache; cough; mouth ulcers; diarrhea; vomiting, acne; skin rash; feeling tired; fever; menstrual disorders such as: absence of menstrual periods (amenorrhea) or irregular periods, sore throat (inflammation of the pharynx/pharyngitis); headache, dizziness (signs of high blood pressure (hypertension)).

Common side effects - side effects that occur in 1-10 out of 100 users:

Middle ear infection; swollen and bleeding gums (signs of infection of the gums (gingivitis)); inflammation of the skin (cellulitis); high level of fats in the blood (hyperlipidemia, raised triglycerides); low level of phosphate in the blood (hypophosphatemia); high level of sugar in the blood (hyperglycemia); tiredness, shortness of breath, 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 platelet count (thrombocytopenia)); pain in the mouth; nose bleeding; abdominal discomfort such as nausea; abdominal pain; severe pain in the lower abdomen and pelvic area that may be acute, with menstrual irregularities (ovarian cyst); excess amount of gas in the intestines (bloating); constipation; abdominal pain, nausea, vomiting, diarrhea, swelling of the abdomen (signs of inflammation of the mucous membrane lining the stomach also known as gastritis or viral gastroenteritis); dry skin, itching; an inflammatory condition of the skin characterized by redness, itching, cysts exuding liquid which then become crusty, peel or become hardened (dermatitis acneiform); hair loss; protein in the urine; menstrual disorders such as: excess menstrual bleeding (menorrhagia) or vaginal bleeding; sleep problems (insomnia); irritability; aggressiveness; high level of an enzyme in the blood called lactate dehydrogenase that provides information about the health of certain organs; higher level in the blood of the hormone that triggers ovulation (increased luteinizing hormone, LH); weight loss.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

Muscle spasms, fever, red-brown urine (these are possible signs of a muscle disorder (rhabdomyolysis)); cough with phlegm, chest pain, fever (signs of inflammation of airways also called viral bronchitis); disturbed taste; menstrual disorders such as delayed periods; higher level in the blood of female reproductive hormone (increase in follicle stimulating hormone, FSH).

Side effects with unknown frequency (effects whose frequency has not yet been determined)

A reaction in an area previously treated by radiotherapy, such as skin redness or pneumonitis (called 'radiation recall syndrome'); worsening of radiotherapy side effects.

If these side effects worsen, please contact the doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear several days after stopping treatment.

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

Hepatitis B reactivation has been diagnosed in several patients taking Everolimus Teva. Inform the doctor if you experience symptoms of hepatitis B during treatment with the medicine. The initial symptoms can include fever, skin rash, joint pain and inflammation. Other symptoms may include tiredness, loss of appetite, nausea, jaundice (yellowing of the skin) and upper right abdominal pain. Pale stools or dark urine can also be signs of jaundice.

Reporting of side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il) which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage:

Store below 25°C.

Store in the original package to protect from light.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

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

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

Everolimus Teva 2.5 mg: A white, flat, rectangular tablet with beveled edges. One side of the tablet is debossed with "EV" and the other side is debossed with "2.5".

Everolimus Teva 5 mg: A white, flat, rectangular tablet with beveled edges. One side of the tablet is debossed with "EV" and the other side is debossed with "5".

Everolimus Teva 7.5 mg: A white, flat, rectangular tablet with beveled edges. One side of the tablet is debossed with "EV" and the other side is debossed with "7.5".

Everolimus Teva 10 mg: A white, flat, rectangular tablet with beveled edges. One side of the tablet is debossed with "EV" and the other side is debossed with "10".

Each package contains 10, 30, 50, 60, 90 tablets. Not all package sizes may be marketed.

Name and address of marketing authorization holder and manufacturer:

Teva Israel Ltd.,124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in June 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

Everolimus Teva 2.5 mg: 163.28.35376.

Everolimus Teva 5 mg: 163.29.35377.

Everolimus Teva 7.5 mg: 163.30.35378.

Everolimus Teva 10 mg: 163.31.35379.

You may contact the marketing authorization holder for a printed leaflet in English at: Tevacare@med-trix.com or by telephone: 1-800-805-005

EVEROLIMUS TABS PIL MW0623

teva