

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor’s prescription only.

AFINITOR® Tablets 2.5 mg, 5 mg, 10 mg

Each tablet contains:

Afinitor 2.5 mg: Everolimus 2.5 mg

Afinitor 5 mg: Everolimus 5 mg

Afinitor 10 mg: Everolimus 10 mg

Inactive ingredients and allergens: See section 6 “Further Information”.

Afinitor contains lactose.

Read this leaflet carefully in its entirety before using the medicine. Keep this leaflet. You may need to read it again. This leaflet contains concise information about the 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.

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

Afinitor is intended to treat children and adolescents who have normal liver function and brain tumors of the SEGA type associated with Tuberous Sclerosis Complex (TSC).

The safety and efficacy of Afinitor in children below the age of 1 year with brain tumors of the SEGA type associated with Tuberous Sclerosis Complex (TSC) have not been established. No data are available.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Afinitor Tablets 2.5, 5 and 10 mg:

- Treatment of patients with a brain tumor of the Subependymal Giant Cell Astrocytoma (SEGA) type associated with Tuberous Sclerosis Complex - TSC.
- 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.
- For treatment of advanced kidney cancer (Advanced Renal Cell Carcinoma [RCC]), where other treatments (so-called “VEGF-targeted therapy”) have not helped stop your disease.
- For the 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-tumor 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 brain tumor cells of the SEGA type, the latter two tumors are caused by a genetic disorder called Tuberous Sclerosis Complex (TSC).

If you have further questions regarding Afinitor or why this medicine has been prescribed for you, consult your doctor.

2. BEFORE USING THE MEDICINE

Afinitor will only be prescribed to you by a doctor with experience in using anticancer therapies or 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.

<p>▯ Do not use the medicine if:</p> <ul style="list-style-type: none">You are allergic (hypersensitive) to everolimus, to similar drugs, such as sirolimus (rapamycin), temsirolimus or to any of the additional ingredients contained in the medicine and detailed in section 6 “Further Information” in this leaflet. <p>In this case, inform the doctor without taking Afinitor.</p> <p>If you think you are allergic, consult with the doctor.</p>

Special warnings regarding use of the medicine:

▯ **Before beginning treatment with Afinitor, tell the doctor if** one of the following conditions applies to you:

- If you have any problems with your liver or have previously had any diseases which may have affected your liver. In such a case, it may be necessary for the doctor to modify the dosage of Afinitor you take or to stop the treatment temporarily or permanently.
- If you have diabetes (high levels of sugar in the blood). Treatment with Afinitor may cause an elevation in blood sugar levels and worsen diabetes. This may lead to a need for medicinal treatment such as insulin and/or oral anti-diabetic agent therapy. Tell the doctor if you experience increased thirst or an increase in the frequency of passing urine.
- If you are scheduled to receive any vaccination during treatment with Afinitor, it is possible that the vaccination will 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 beginning treatment with Afinitor.
- If you have high levels of cholesterol, Afinitor can increase the level of cholesterol and/or other blood fats.
- If 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.
- If you have any infections. It may be necessary to treat your infection before starting treatment with Afinitor.
- If you have previously had hepatitis B, because it may be reactivated during your treatment with Afinitor (see section 4: “Side effects”).
- If you suffer or have suffered in the past from kidney problems.

Afinitor may also:

- Cause mouth sores (oral ulcerations).
- 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 infection, consult your doctor.
- 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”).

Inform your doctor immediately if you experience these symptoms.

▯ **Taking other medicines**

Afinitor may interfere with the efficacy of other medicines. If you are taking other medicines at the same time as Afinitor, it is possible that your doctor will 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 medicines and food supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking the following medicines:

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

- Medicines used to treat fungal infections, anti-fungal medicines such as: ketoconazole, itraconazole, voriconazole, fluconazole.
- Medicines to treat types of bacterial infections, antibiotics such as: clarithromycin, telithromycin or erythromycin.
- Medicines used to treat AIDS (HIV) such as: ritonavir.
- Some medicines used to treat heart conditions or high blood pressure such as: verapamil or diltiazem.
- A medicine used to help 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.
- St. John’s Wort - an herbal medicine used to treat depression and other conditions (also known as *Hypericum Perforatum*).
- Certain corticosteroids used to treat a wide variety of conditions including inflammatory or immune problems such as: dexamethasone.
- Medicines which stop seizures or epileptic fits, anti-epileptics such as: phenytoin, carbamazepine or phenobarbital.
- Efavirenz, nevirapine - used to treat AIDS (HIV).

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 require a change in Afinitor dosage. Your doctor will decide this. If the dosage of your anti-seizure medicine changes, please inform your doctor.

▯ **Use of the medicine and food**

You should take Afinitor every day at the same time, either consistently with food or consistently without food.

Do not drink grapefruit juice or eat grapefruits during treatment with Afinitor.

▯ **Older people (age 65 years and over)**

If you are aged 65 years or over, you can take Afinitor at the same dosage as younger adults.

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

Pregnancy

Afinitor could harm the fetus and is therefore not recommended during pregnancy. Tell your doctor if you are pregnant or think that you may be pregnant.

Women of child-bearing potential

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

Breast-feeding

Afinitor could harm a baby. Do not breast-feed during treatment with Afinitor. Tell your doctor if you are breast-feeding.

If you are pregnant or breast-feeding, consult the doctor or pharmacist before beginning treatment with any medicine.

Fertility

Afinitor may have an impact on male and female fertility. Absence of periods in females who previously had periods (amenorrhea) has been observed in some female patients receiving Afinitor. If you are interested in becoming pregnant – consult the doctor.

▯ **Driving and using machinery**

Exercise caution regarding driving or operating dangerous machinery during treatment with this medicine. This is especially true if you feel fatigued, since excessive fatigue is a 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 according to the doctor’s instructions.

Check with the doctor or pharmacist if you are not sure.

The dosage and manner of treatment will be determined by the doctor only. Do not take more than the doctor has instructed you. Do not change the dosage without consulting with the doctor.

If you suffer from certain 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.

When to take Afinitor

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

How to take Afinitor

Afinitor Tablets are to be taken by mouth.

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

If you are taking Afinitor Tablets for the treatment of 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) 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. Wash hands thoroughly before and after preparation of the suspension.

Tests and Follow-up

Before and during treatment with Afinitor, you should have regular 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 adverse effect on these cells. In addition, tests will be performed to monitor your kidney function (levels of creatinine in the blood, blood urea nitrogen or protein in the urine), liver function (level of transaminases in the blood) and blood sugar, lipid and cholesterol levels, because these can all be affected by Afinitor.

If you receive Afinitor for the treatment of a brain tumor of the SEGA type associated with Tuberous Sclerosis Complex - TSC, regular blood tests are necessary to measure how much Afinitor is in your blood, since this will help your doctor decide how much Afinitor you need to take.

If you accidentally take too high a dosage

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

If you forget to take the medicine

If you forget to take the medicine at the designated time, take your next dose as scheduled. **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.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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. Afinitor may also affect the results of some blood tests.

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
- Severe itching of the skin, with a red rash or raised bumps

Some side effects could be serious:

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

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

Very common side effects, effects that may occur in more than 1 out of 10 users

- Increased body temperature or chills (signs of infection)
- Fever, coughing, difficulty breathing, wheezing, signs of inflammation of the lung (pneumonitis)

Common side effects, effects that may occur in up to 1 out of 10 users

- Excessive thirst, high urine output, increased appetite with weight loss, tiredness (signs of diabetes)
- Bleeding (hemorrhage), e.g. in the gut wall
- Severely decreased urine output, signs of kidney failure (renal failure)

Uncommon side effects, effects that may occur in up to 1 out of 100 users

- Fever, skin rash, joint pain and inflammation, fatigue, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stool, dark urine (may also 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 blockade of 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)
- 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, hypersensitivity)

Rare side effects, effects that may occur in up to 1 out of 1,000 users

- Shortness of breath or rapid breathing (signs of acute respiratory distress syndrome)
- Swelling of the airways or tongue, with or without respiratory impairment (angioedema)

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

Serious side effects observed during the treatment in patients with a kidney tumor known as Angiomyolipoma associated with Tuberous Sclerosis Complex and in patients with a brain tumor of the Subependymal Giant Cell Astrocytoma type associated with Tuberous Sclerosis Complex.

Very common side effects, effects that may occur in more than 1 out of 10 users

- Fever, coughing, difficulty breathing, wheezing, signs of inflammation of the lung (pneumonia)

Common side effects, effects that may occur in up to 1 out of 10 users

- Swelling, feeling of heaviness or tightness, pain, limited mobility of body parts (potential sign of abnormal buildup of fluid in soft tissue due to a blockage in the lymphatic system - lymphedema)
- Rash of small fluid-filled blisters appearing on reddened skin, signs of viral infection that can potentially be severe (herpes zoster)
- Fever, coughing, difficulty breathing, wheezing, signs of inflammation of the lung (pneumonitis)

Uncommon side effects, effects that may occur in up to 1 out of 100 users

- Rash, itching, hives, difficulty breathing or swallowing, dizziness, signs of serious allergic reaction (hypersensitivity)

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 observed during treatment of hormone receptor-positive advanced breast cancer, advanced kidney cancer or advanced neuroendocrine tumors of pancreatic, gastrointestinal or lung origin:

Very common side effects, effects that may occur in more than 1 out of 10 users

High levels of sugar in the blood (hyperglycemia); loss of appetite; disturbed taste; headache; nose bleeds; cough; mouth ulcers; stomach upsets including nausea, diarrhea; skin rash; itching (pruritus); 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).

If any of the side effects listed above affect you severely, **tell your attending doctor.**

Common side effects, effects that may occur in up to 1 out of 10 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); fever, sore throat or 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, guts; 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 peeling, skin bruising; nail disorders, brittle nails; hair loss; abnormal liver blood tests (increased alanine and aspartate aminotransferase); abnormal renal blood tests (increased creatinine); protein in the urine; discharge from the eyes accompanied by itching, redness and swelling.

If any of the side effects listed above affect you severely, **tell your attending doctor.**

Uncommon side effects, effects that may occur in up to 1 out of 100 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); absence of periods (amenorrhea); passing urine more often during daytime; chest pain; abnormal wound healing; hot flushes; pink or red eye (conjunctivitis).

If any of the side effects listed above affect you severely, **tell your attending doctor.**

Rare side effects, effects that may occur in up to 1 out of 1,000 users

Tiredness, breathlessness, dizziness, pale skin [signs of low levels of red blood cells (a type of anemia called pure red cell aplasia)].

If these side effects get worse, please tell your doctor, pharmacist, or healthcare provider. Most of the side effects are mild to moderate and will generally disappear after a few days of treatment interruption.

Other side effects observed during treatment of Tuberous Sclerosis Complex:

Very common side effects, effects that may occur in more than 1 out of 10 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); middle ear infection; high level of lipids (fats) in the blood (hypercholesterolemia); mouth ulcers; acne; menstruation disorders such as absence of periods (amenorrhea), irregular periods.

If any of the side effects listed above affect you severely, **tell your attending doctor.**

Common side effects, effects that may occur in up to 1 out of 10 users

Urinary tract infection; swollen, bleeding gums, signs of gum inflammation (gingivitis); skin inflammation (cellulitis); sore throat (pharyngitis); 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); decreased appetite; 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); headache, dizziness, signs of high blood pressure (hypertension); headache; disturbed taste; spontaneous bleeding or bruising, signs of low level of platelets (thrombocytopenia); cough; mouth pain; nose bleeds; inflammation of the stomach lining (gastritis); diarrhea; vomiting; 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 (gastritis, viral gastroenteritis); dry skin; skin rash; an inflammatory condition of the skin characterized by redness, itching, and oozing liquid-filled cysts which become scaly, crusted, or hardened (dermatitis acneiform); hair loss; protein in the urine; menstruation disorders such as delayed periods, heavy periods (menorrhagia), or vaginal bleeding; feeling tired; irritability; aggression; fever; high level of an enzyme called lactate dehydrogenase in the blood that gives information about the health of certain organs; higher level of ovulation triggering hormone in the blood (increased Luteinizing Hormone - LH); weight loss.

If any of the side effects listed above affect you severely, **tell your attending doctor.**

Uncommon side effects, effects that may occur in up to 1 out of 100 users

Muscle spasm, fever, red-brown urine, these are possibly signs of muscle disorder (rhabdomyolysis); cough with phlegm, chest pain, fever, signs of inflammation of airways (viral bronchitis); insomnia; higher blood level of female reproductive hormone (increase in Follicle Stimulating Hormone - FSH).

If these side effects get worse, please tell your doctor, pharmacist, or healthcare provider. 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 one of the side effects 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 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 and drug interactions in children:

Parents must inform the attending doctor about any side effects, as well as any additional medicines being given to the child!

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) that directs you to the online form for reporting side effects,

or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe 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 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.
- Do not store above 25°C.
- Store in the original package in order to protect from light and moisture. Do not use if you notice that the package is damaged.
- Open the blister (tray) pack immediately before taking Afinitor tablets.

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, the medicine also contains:**

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

Each Afinitor 2.5 mg tablet contains 71.875 mg lactose anhydrous and 2.450 mg lactose monohydrate.

Each Afinitor 5 mg tablet contains 143.75 mg lactose anhydrous and 4.90 mg lactose monohydrate.

Each Afinitor 10 mg tablet contains 287.50 mg lactose anhydrous and 9.80 mg lactose monohydrate.

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

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

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

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

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

Each package contains 30 tablets.

▯ **Registration Holder and address:** Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

▯ **Manufacturer and address:** Novartis Pharma Stein AG, Switzerland for Novartis Pharma AG, Basel, Switzerland.

- This leaflet was checked and approved by the Ministry of Health in August 2016

▯ Registration numbers of the medicine in