Package leaflet: Information for the patient

Everolimus Teva
2.5 mg, 5 mg, 7.5 mg and 10 mg Tablets
everolimus

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Everolimus Teva is and what it is used for

Everolimus Teva is an anticancer medicine containing the active substance everolimus. Everolimus reduces the blood supply to the tumour and slows down the growth and spread of cancer cells.

Everolimus Teva is used to treat adult patients with:

- Hormone receptor-positive advanced breast cancer in postmenopausal women, in whom other treatments (so called 'non-steroidal aromatase inhibitors') no longer keep the disease under control. It is given together with a medicine called exemestane, a steroidal aromatase inhibitor, which is used for hormonal anticancer therapy.
- Advanced tumours called neuroendocrine tumours that originate from the stomach, bowels, lung or pancreas. It is given if the tumours are inoperable and do not overproduce specific hormones or other related natural substances.
- Advanced kidney cancer (advanced renal cell carcinoma), where other treatments (so-called 'VEGF-targeted therapy') have not helped stop your disease.

Everolimus Teva is an anti-tumour medicine which can block certain cells in the body from growing. It contains an active substance called everolimus which may reduce the size of kidney tumours called renal angiomyolipomas and brain tumours called subependymal giant cell astrocytomas (SEGA). These tumours are caused by a genetic disorder called tuberous sclerosis complex (TSC).
Everolimus Teva is used to treat:
- TSC with angiomyolipoma of the kidney in adults who do not require immediate surgery.
- SEGA associated with TSC in adults and children for whom surgery is not appropriate.

2. What you need to know before you take Everolimus Teva

Breast cancer/Neuroendocrine tumours/Kidney cancer
Everolimus Teva will only be prescribed for you by a doctor with experience in cancer treatment.
Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Angiomyolipoma of the kidney/SEGA
If you are being treated for TSC with angiomyolipoma of the kidney, Everolimus Teva will only be prescribed for you by a doctor with experience in treating patients with TSC.
If you are being treated for SEGA associated with TSC, Everolimus Teva will only be prescribed by a doctor with experience in treating patients with SEGA and with access to blood tests which will measure how much everolimus is in your blood.
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 Teva or why it has been prescribed for you, ask your doctor.

Do NOT take Everolimus Teva:
- **if you are allergic** to everolimus, to related substances such as sirolimus or temsirolimus, or to any of the other ingredients of this medicine (listed in section 6).

If you had allergic reactions before or if you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor before taking Everolimus Teva if you:
- have any problems with your liver or if you have ever had any disease which may have affected your liver. If this is the case, your doctor may need to prescribe a different dose of Everolimus Teva or stop treatment, either for a short time or permanently.
- have diabetes (high level of sugar in your blood). Everolimus Teva may increase blood sugar levels and worsen diabetes mellitus. This may result in the need for insulin and/or oral antidiabetic agent therapy. Tell your doctor if you experience any excessive thirst or increased frequency of urination.
- need to receive a vaccine while taking Everolimus Teva as vaccination may be less effective.
  Angiomyolipoma of the kidney/SEGA
  For children with SEGA, it is important to have a discussion with the doctor about the childhood vaccination program before treatment with Everolimus Teva.
- have high cholesterol. Everolimus Teva may elevate cholesterol and/or other blood fats.
- have had recent major surgery, or if you still have an unhealed wound following surgery. Everolimus Teva may increase the risk of problems with wound healing.
- have an infection. It may be necessary to treat your infection before starting Everolimus Teva.
- have previously had hepatitis B, because this may be reactivated again during treatment with Everolimus Teva (see section 4 'Possible side effects')
- have received or are about to receive radiation therapy.

Everolimus Teva may also:
- weaken your immune system. Therefore, you may be at risk of getting an infection while you are taking Everolimus Teva. If you have fever or other signs of an infection, consult with 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 Everolimus Teva.
- cause shortness of breath, cough and fever (see section 4 "Possible side effects").
- cause mouth ulcers and sores to develop. Your doctor might need to interrupt or discontinue your treatment with Everolimus Teva. You might need treatment with a mouthwash, gel or other products. 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 Teva at the same dose or at a lower dose.
- cause complications of radiation therapy. Severe complications of radiotherapy (such as shortness of breath, nausea, diarrhoea, 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.

Tell your doctor immediately if you experience these symptoms.

You will have blood tests before and periodically during treatment. These will check the amount of blood cells (white blood cells, red blood cells and platelets) in your body to see if Everolimus Teva 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 (level of transaminases) and your blood sugar and lipid levels. This is because these can also be affected by Everolimus Teva.

Angiomyolipoma of the kidney/SEGA
If you receive Everolimus Teva for the treatment of SEGA associated with TSC, regular blood tests are also necessary to measure how much everolimus is in your blood since this will help your doctor decide how much Everolimus Teva you need to take.

Children and adolescents
Breast cancer/Neuroendocrine tumours/Kidney cancer
Everolimus Teva is NOT to be used in children or adolescents (age below 18 years).
Angiomyolipoma of the kidney/SEGA
Everolimus Teva can be used in children and adolescents SEGA associated with TSC.
Everolimus Teva is NOT to be used in children or adolescents with TSC who have angiomyolipoma of the kidney in the absence of SEGA, as it has not been studied in such patients.

Other medicines and Everolimus Teva
Everolimus Teva may affect the way some other medicines work. If you are taking other medicines at the same time as Everolimus Teva, your doctor may need to change the dose of Everolimus Teva or the other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following may increase the risk of side effects with Everolimus Teva:
- ketoconazole, itraconazole, voriconazole or fluconazole and other antifungals used to treat fungal infections
- clarithromycin, telithromycin or erythromycin, antibiotics used to treat bacterial infections
- ritonavir and other medicines used to treat HIV infection/AIDS
- verapamil or diltiazem, used to treat heart conditions or high blood pressure
- dronedarone, a medicine used to help regulate your heartbeat
- ciclosporin, a medicine used to stop the body from rejecting organ transplants
- cannabidiol (uses amongst others include treatment of seizures)
- imatinib, used to inhibit the growth of abnormal cells
- angiotensin-converting enzyme (ACE) inhibitors (such as ramipril) used to treat high blood pressure or other cardiovascular problems
- nefazodone, used to treat depression.

The following may reduce the effectiveness of Everolimus Teva:
- rifampicin, used to treat tuberculosis (TB)
- efavirenz or nevirapine, used to treat HIV infection/AIDS
- St John's Wort (*Hypericum perforatum*), a herbal product used to treat depression and other conditions
- dexamethasone, a corticosteroid used to treat a wide variety of conditions including inflammatory or immune problems
- phenytoin, carbamazepine or phenobarbital and other anti-epileptics used to stop seizures or fits.

All medicines listed above should be avoided during your treatment with Everolimus Teva. If you are taking any of them, your doctor may switch you to a different medicine, or may change your dose of Everolimus Teva.

Angiomyolipoma of the kidney/SEGA
If you are taking an anti-seizure medicine, a change in the dose of the anti-seizure medicine (increase or decrease) may make a change in the Everolimus Teva dose necessary. Your doctor will decide this. If the dose of your anti-seizure medicine changes, please inform your doctor.

Everolimus Teva with food and drink
Avoid grapefruit and grapefruit juice while you are on Everolimus Teva. It may increase the amount of everolimus in the blood, possibly to a harmful level.

Pregnancy, breast-feeding and fertility

Pregnancy
Everolimus Teva could harm an unborn baby and is not recommended during pregnancy. Tell your doctor if you are pregnant or think that you may be pregnant.

Breast cancer/Neuroendocrine tumours/Kidney cancer
Your doctor will discuss with you whether you should take this medicine during your pregnancy.

Women who could potentially become pregnant must use highly effective contraception during treatment and for up to 8 weeks after ending treatment. If, despite these measures, you think you may have become pregnant, ask your doctor for advice **before** taking any more Everolimus Teva.

Breast-feeding
Everolimus Teva could harm a breast-fed baby. You should NOT breast-feed during treatment and for 2 weeks after the last dose of Everolimus Teva. Tell your doctor if you are breast-feeding.

Fertility
Everolimus Teva may affect male and female fertility. Talk to your doctor if you wish to have children.

Breast cancer/Neuroendocrine tumours/Kidney cancer
Absence of menstrual periods (amenorrhoea) has been observed in some female patients receiving everolimus.

Driving and using machines
If you feel unusually tired (fatigue is a very common side effect), take special care when driving or using machines.

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

3. How to take Everolimus Teva

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Breast cancer/Neuroendocrine tumours/Kidney cancer

The recommended dose is 10 mg, taken once a day. Your doctor will tell you how many tablets of Everolimus Teva to take.

If you have liver problems, your doctor may start you on a lower dose of Everolimus Teva (2.5, 5 or 7.5 mg per day).

Angiomyolipoma of the kidney/SEGA

If you receive Everolimus Teva for the treatment of TSC with angiomyolipoma of the kidney, the usual dose is 10 mg, to be taken once daily.
A higher or lower dose may be recommended by your doctor based on your individual treatment needs, for example if you have problems with your liver or if you are taking certain other medicines in addition to Everolimus Teva.

If you receive Everolimus Teva for the treatment of TSC with SEGA, your doctor will determine the dose of Everolimus Teva you need to take depending on:
- your age
- your body size
- the health of your liver
- other medicines you are taking.

You will have blood tests during treatment with Everolimus Teva. This is to measure the amount of everolimus in your blood and find the best daily dose for you.

If you experience certain side effects while you are taking Everolimus Teva (see section 4), your doctor may lower your dose or stop treatment, either for a short time or permanently.

Take Everolimus Teva once a day, at about the same time every day. You can take the tablets either with or without food, but you need to do this in the same way each day.

Swallow the tablet(s) whole with a glass of water. Do NOT chew or crush the tablets.

Angiomyolipoma of the kidney/SEGA
If you are taking Everolimus Teva for the treatment of TSC with SEGA and if you are unable to swallow the tablets, you can stir them into a glass of water:
- Put the required number of tablets into a glass of water (approximately 30 ml).
- Gently stir the contents of the glass until the tablets break apart (approximately 8.5 minutes) and then drink the contents immediately.
- Refill the glass with the same amount of water (approximately 30 ml), gently stir the remaining content and drink the whole amount to make sure that you get the full dose of Everolimus Teva.
- If necessary, drink additional water to wash out any residues in your mouth.

Special information for caregivers
Caregivers are advised to avoid contact with suspensions of Everolimus Teva tablets. Wash hands thoroughly before and after preparation of the suspension.

If you take more Everolimus Teva than you should
If you have taken too much Everolimus Teva, or if someone else accidentally takes your tablets, see a doctor or go to a hospital **immediately**. Urgent treatment may be necessary.
Take the carton and this leaflet, so that the doctor knows what has been taken.

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

If you stop taking Everolimus Teva
Do NOT stop taking Everolimus Teva unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Breast cancer/Neuroendocrine tumours/Kidney cancer

STOP taking Everolimus Teva and seek medical help immediately if you experience any of the following signs of an allergic reaction:
- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Serious side effects of Everolimus Teva include:

Very common (may affect more than 1 in 10 people)
- increased temperature, chills (signs of infection)
- fever, coughing, difficulty breathing, wheezing (signs of inflammation of the lung, also known as pneumonitis).

Common (may affect up to 1 in 10 people)
- excessive thirst, high urine output, increased appetite with weight loss, tiredness (signs of diabetes)
- bleeding (haemorrhage), for example in the gut wall
- severely decreased urine output (sign of kidney failure).

Uncommon (may affect up to 1 in 100 people)
- fever, skin rash, joint pain and inflammation, as well as 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)
- 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, also known as hypersensitivity).

Rare (may affect up to 1 in 1,000 people)
- shortness of breath or rapid breath (signs of acute respiratory distress syndrome).

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

Other possible side effects of Everolimus Teva include:

Very common (may affect more than 1 in 10 people)
- high level of sugar in the blood (hyperglycaemia)
- loss of appetite
- disturbed taste (dysgeusia)
- headache
- nose bleeds (epistaxis)
- cough
- mouth ulcers
- upset stomach including feeling sick (nausea) or diarrhoea
- skin rash
- itching (pruritus)
- feeling weak or tired
- tiredness, breathlessness, dizziness, pale skin, signs of low level of red blood cells (anaemia)
- swelling of arms, hands, feet, ankles or other part of the body (signs of oedema)
- weight loss
- high level of lipids (fats) in the blood (hypercholesterolaemia).

Common (may affect up to 1 in 10 people)
- spontaneous bleeding or bruising (signs of low level of platelets, also known as thrombocytopenia)
- breathlessness (dyspnoea)
- thirst, low urine output, dark urine, dry flushed skin, irritability (signs of dehydration)
- trouble sleeping (insomnia)
- headache, dizziness (sign of high blood pressure, also known as hypertension)
- swelling of part or all of your arm (including fingers) or leg (including toes), feeling of heaviness, restricted movement, discomfort (possible symptoms of lymphoedema)
- fever, sore throat, mouth ulcers due to infections (signs of low level of white blood cells, leukopenia, lymphopenia and/or neutropenia)
- fever
- inflammation of the inner lining of the mouth, stomach, gut
- dry mouth
- heartburn (dyspepsia)
- being sick (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)
- reddening of the skin (erythema)
- joint pain
- pain in the mouth
- menstruation disorders such as irregular periods
- high level of lipids (fats) in the blood (hyperlipidaemia, raised triglycerides)
- low level of potassium in the blood (hypokalaemia)
- low level of phosphate in the blood (hypophosphataemia)
- low level of calcium in the blood (hypocalcaemia)
- dry skin, skin exfoliation, skin lesions
- nail disorders, breaking of your nails
- mild loss of hair
- 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 (may affect up to 1 in 100 people)
- weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells, also known as pancytopenia)
- loss of sense of taste (ageusia)
- coughing up blood (haemoptysis)
- menstruation disorders such as absence of periods (amenorrhoea)
- passing urine more often during daytime
- chest pain
- abnormal wound healing
- hot flushes
- discharge from the eye with itching and redness, pink eye or red eye (conjunctivitis).

Rare (may affect up to 1 in 1,000 people)
- tiredness, breathlessness, dizziness, pale skin (signs of low level of red blood cells, possibly due to a type of anaemia 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.

Not known (frequency cannot be estimated from the available data)
- 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 tell your doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear if your treatment is interrupted for a few days.

Angiomyolipoma of the kidney/SEGA

STOP taking Everolimus Teva and seek medical help immediately if you or your child experiences 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 Everolimus Teva include:

Very common (may affect more than 1 in 10 people)
- fever, cough, difficulty breathing, wheezing (signs of inflammation of the lung due to infection, also known as pneumonia).

Common (may affect up to 1 in 10 people)
- swelling, feeling of heaviness or tightness, pain, limited mobility of body parts (this could occur anywhere in the body and is a potential sign of an abnormal build-up of fluid in soft tissue due to a blockage in the lymphatic system, also known as lymphoedema)
- rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of serious allergic reaction, also known as hypersensitivity)
- fever, cough, difficulty breathing, wheezing (signs of inflammation of the lung, also known as pneumonitis).

Uncommon (may affect up to 1 in 100 people)
- 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 this might have life-threatening consequences.

Other possible side effects of Everolimus Teva include:

Very common (may affect more than 1 in 10 people)
- 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, also known as sinusitis)
- urinary tract infection
- high level of lipids (fats) in the blood (hypercholesterolaemia)
- decreased appetite
- headache
- cough
- mouth ulcers
- diarrhoea
- being sick (vomiting)
- acne
- skin rash
- feeling tired
- fever
- menstruation disorders such as absence of periods (amenorrhoea) or irregular periods
- sore throat (pharyngitis)
- headache, dizziness, signs of high blood pressure (hypertension).

Common (may affect up to 1 in 10 people)
- middle ear infection
- swollen, bleeding gums (signs of gum inflammation, also known as gingivitis)
- skin inflammation (cellulitis)
- high level of lipids (fats) in the blood (hyperlipidaemia, raised triglycerides)
- low level of phosphate in the blood (hypophosphataemia)
- high level of sugar in the blood (hyperglycaemia)
- tiredness, breathlessness, dizziness, pale skin (signs of low level of red blood cells, also known as anaemia)
- fever, sore throat or mouth ulcers due to infections (signs of low level of white blood cells, also known as leucopenia, lymphopenia, neutropenia)
- spontaneous bleeding or bruising (signs of low level of platelets, also known as thrombocytopenia)
- mouth pain
- nose bleeds (epistaxis)
- stomach upset like feeling sick (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, diarrhoea, swelling and bloating of the abdomen (signs of inflammation of the stomach lining, also known as gastritis or gastroenteritis viral)
- dry skin, itching (pruritus)
- an inflammatory condition of the skin characterised by redness, itching, and oozing liquid-filled cysts which become scaly, crusted, or hardened (dermatitis acneiform)
- loss of hair (alopecia)
- protein in the urine
- menstruation disorders such as heavy periods (menorrhagia) or vaginal bleeding
- trouble sleeping (insomnia)
- irritability
- aggression
- high level of an enzyme called blood lactate dehydrogenase that gives information about the health of certain organs
- high level of the hormone that triggers ovulation (blood luteinising hormone increased)
- weight loss.

Uncommon (may affect up to 1 in 100 people)
- muscle spasms, fever, red-brown urine which may be symptoms of a muscle disorder (rhabdomyolysis)
- cough with phlegm, chest pain, fever (signs of inflammation of airways, also known as bronchitis viral)
- disturbed taste (dysgeusia)
- menstruation disorders such as delayed periods
- higher level of female reproductive hormone (blood follicle stimulating hormone increased).

Not known (frequency cannot be estimated from the available data)
- 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 tell your doctor and/or pharmacist. Most of the side effects are mild to moderate and will generally disappear if your treatment is interrupted for a few days.

The following side effects have been reported in patients taking everolimus for the treatment of conditions other than TSC:
- kidney disorders: altered frequency or absence of urination may be symptoms of kidney failure and have been observed in some patients receiving everolimus. Other symptoms may include altered kidney function test (increase in creatinine).
- symptoms of heart failure such as breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- blockage or obstruction of a blood vessel (vein) in the leg (deep vein thrombosis). Symptoms may include swelling and/or pain in one of your legs, usually in the calf, redness or warm skin in the affected area.
- problems with wound healing
- high levels of sugar in the blood (hyperglycaemia).

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Everolimus Teva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

7.5 mg
This medicine does not require any special temperature storage conditions.

2.5 mg / 5 mg / 10 mg
Do not store above 25°C.

Open the blister just before taking the tablets. Do not use this medicine if any pack is damaged or shows signs of tampering.

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

6. Contents of the pack and other information

What Everolimus Teva Tablets contains
The active substance is everolimus.
- Everolimus Teva 2.5 mg Tablets contains 2.5 mg of everolimus.
- Everolimus Teva 5 mg Tablets contains 5 mg of everolimus.
- Everolimus Teva 7.5 mg Tablets contains 7.5 mg of everolimus.
- Everolimus Teva 10 mg Tablets contains 10 mg of everolimus.

The other ingredients are butylhydroxytoluene (E 321), hypromellose, lactose monohydrate, lactose, crospovidone and magnesium stearate.

What Everolimus Teva Tablets looks like and contents of the pack
Everolimus Teva 2.5 mg Tablets are white, oblong, flat, bevelled edge tablets, approximately 10mm long and 4mm wide, marked with 'EV' on one side and '2.5' on the other.
Everolimus Teva 5 mg Tablets are white, oblong, flat, bevelled edge tablets, approximately 12mm long and 5mm wide, marked with 'EV' on one side and '5' on the other.
Everolimus Teva 7.5 mg Tablets are white, oblong, flat, bevelled edge tablets, approximately 14mm long and 5.5mm wide, marked with 'EV' on one side and '7.5' on the other.
Everolimus Teva 10 mg Tablets are white, oblong, flat, bevelled edge tablets, approximately 15mm long and 6mm wide, marked with 'EV' on one side and '10' on the other.

Everolimus Teva is available in blister packs containing 10, 30, 30x1, 50x1, 60 or 90 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

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