

Package leaflet: Information for the patient

Everolimus Teva 2.5 mg Tablets

Everolimus Teva 5 mg Tablets

Everolimus Teva 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
2. What you need to know before you take Everolimus Teva
3. How to take Everolimus Teva
4. Possible side effects
5. How to store Everolimus Teva
6. Contents of the pack and other information

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:

- **Advanced tumours** called neuroendocrine tumours that originate from the stomach, bowels, lung. It is given if the tumours are inoperable and do not overproduce specific hormones or other related natural substances.

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

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. 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 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.

- if you 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.
- if you need to receive a vaccine while taking Everolimus Teva.
- if you have high cholesterol. Everolimus Teva may elevate cholesterol and/or other blood fats.
- if you 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.
- if you have an infection. It may be necessary to treat your infection before starting Everolimus Teva.
- if you have previously had hepatitis B, because this may be reactivated during treatment with Everolimus Teva (see section 4 ‘Possible side effects’).

Everolimus Teva may also:

- weaken your immune system. Therefore, you may be at risk of getting an infection while you are taking Everolimus Teva.
- 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.

Tell your doctor if you experience these symptoms.

You will have regular blood tests 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 (level of creatinine) and liver function (level of transaminases) and your blood sugar and cholesterol levels. This is because these can also be affected by Everolimus Teva.

Children and adolescents

Everolimus Teva is NOT to be used in children or adolescents (age below 18 years).

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 heart beat
- ciclosporin, a medicine used to stop the body from rejecting organ transplants
- 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.

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.

These medicines 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.

Everolimus Teva with food and drink

You should take Everolimus Teva at the same time every day, consistently either with or without food. Avoid grapefruit and grapefruit juice while you are on Everolimus Teva as taking these together can increase the risk of side effects.

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. Your doctor will discuss with you whether you should take this medicine during your pregnancy.

Women who could potentially become pregnant should use highly effective contraception during 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. Tell your doctor if you are breast-feeding.

Female fertility

Absence of menstrual periods (amenorrhoea) has been observed in some female patients receiving everolimus.

Everolimus Teva may have an impact on female fertility. Talk to your doctor if you wish to have children.

Male fertility

Everolimus Teva may affect male fertility. Talk to your doctor if you wish to father a child.

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

Everolimus Teva contains lactose (milk sugar). 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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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).

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, consistently either with or without food.

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

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.

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)
- 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)
- discharge from the eye with itching, redness and swelling
- 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
- 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.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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. This medicine does not require any special temperature storage conditions.

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 contains:

The active substance is everolimus.

- Everolimus Teva 2.5mg contains 2.5 mg everolimus.
- Everolimus Teva 5mg contains 5 mg everolimus.
- Everolimus Teva 10mg contains 10 mg everolimus.

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

What Everolimus Teva 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 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 and Manufacturers

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

Manufacturers

TEVA Gyógyszergyár Zrt.
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PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)
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Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Everolimus ratiopharm 2,5 mg / 5 mg / 7,5 mg / 10 mg Tabletten
Belgium	Everolimus Teva 2,5 mg / 5 mg / 7,5 mg / 10 mg Tabletten
Bulgaria	Еверолимус Тева 10mg таблетки
Croatia	Everolimus Pliva 2,5 / 5 / 7,5 / 10 mg tablete
Cyprus	Everolimus Teva 2,5 / 5 / 7,5 / 10 mg δισκία
Czech Republic	Everolimus Teva
Denmark	Everolimus Teva
Estonia	Everolimus Teva
Finland	Everolimus ratiopharm 2,5 / 5 / 10 mg tabletti
France	Everolimus Teva 2.5 / 5 / 10 mg comprimé
Germany	Everolimus-ratiopharm 2,5 mg / 5 mg / 7,5 mg / 10 mg Tabletten
Greece	Everolimus Teva 2,5 / 5 / 7,5 / 10 mg δισκία
Hungary	Everolimus Teva 5 / 10 mg tableta
Ireland	Everolimus Teva 2.5 mg, 5 mg & 10 mg Tablets
Italy	Everolimus Teva
Latvia	Everolimus Teva 10 mg tabletes
Netherlands	Everolimus Teva 2,5 / 5 / 10 mg, tabletten
Norway	Everolimus Teva
Poland	Everolimus Teva
Portugal	Everolimus Teva
Slovakia	Everolimus Teva 5 / 7,5 / 10 mg
Slovenia	Everolimus Teva 2,5 / 5 / 7,5 / 10 mg tablete
Spain	Everolimus Teva 2,5 / 5 / 10 mg comprimidos EFG
Sweden	Everolimus Teva
United Kingdom	Everolimus Teva 2.5 mg, 5 mg, 7.5 mg, 10 mg Tablets

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