LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Everolimus Teva
(everolimus)

SE/H/1608/01-04/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Everolimus Teva
(everolimus)

Tablets, 2,5 mg, 5 mg, 7,5 mg and 10 mg

This is a summary of the public assessment report (PAR) for Everolimus Teva. It explains how Everolimus Teva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Everolimus Teva.

For practical information about using Everolimus Teva, patients should read the package leaflet or contact their doctor or pharmacist.

What is Everolimus Teva and what is it used for?

Everolimus Teva 2,5 mg, 5 mg, and 10 mg, tablets are 'generic medicines'. This means that they are similar to a 'reference medicine' already authorised in the European Union (EU) called Afinitor.

Everolimus Teva 7.5 mg, tablet is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Afinitor, but is available in a different strength.

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.

How does Everolimus Teva work?

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.

How is Everolimus Teva used?

The pharmaceutical form of Everolimus Teva is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Everolimus Teva have been shown in studies?

Because Everolimus Teva is a generic/hybrid medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Afinitor. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Everolimus Teva?

Because Everolimus Teva is a generic/hybrid medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet

Why is Everolimus Teva approved?

It was concluded that, in accordance with EU requirements, Everolimus Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine Afinitor. Therefore, the Medical Products Agency in Sweden decided that, as for Afinitor, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Everolimus Teva?

A risk management plan has been developed to ensure that Everolimus Teva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Everolimus Teva, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Everolimus Teva

The marketing authorisation for Everolimus Teva was granted on 2017-08-18 in Sweden.

The full PAR for Everolimus Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Everolimus Teva, please read the [package leaflet – 2.5 mg], [package leaflet – 5 mg], [package leaflet – 7.5 mg], [package leaflet – 10 mg] or contact your doctor or pharmacist.

This summary was last updated in 2017-08.

.