LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Everolimus Ethypharm (everolimus)

SE/H/1707/01-03/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 Ethypharm

(everolimus)

Tablet 2,5 mg, 5 mg and 10 mg

This is a summary of the public assessment report (PAR) for Everolimus Ethypharm. It explains how Everolimus Ethypharm 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 Ethypharm.

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

What is Everolimus Ethypharm and what is it used for?

Everolimus Ethypharm is a 'generic medicine'. This means that Everolimus Ethypharm is similar to a 'reference medicine' already authorised in the European Union (EU) called Afinitor.

Everolimus Ethypharm 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 Ethypharm work?

Everolimus Ethypharm 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 Ethypharm used?

The pharmaceutical form of Everolimus Ethypharm 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 Ethypharm have been shown in studies?

Because Everolimus Ethypharm is a generic 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 Ethypharm?

Because Everolimus Ethypharm is a generic 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 Ethypharm approved?

It was concluded that, in accordance with EU requirements, Everolimus Ethypharm 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 Ethypharm?

A risk management plan has been developed to ensure that Everolimus Ethypharm 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 Ethypharm, 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 Ethypharm

The marketing authorisation for Everolimus Ethypharm was granted on 2018-07-11 in Sweden.

The full PAR for Everolimus Ethypharm can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Everolimus Ethypharm, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-07.