LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Webrix
(afatinib)

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Summary Public Assessment Report

Webrix
afatinib, afatinib dimaleate

Film-coated tablet, 20 mg, 30 mg, 40 mg, 50 mg

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Webrix and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called GIOTRIF.

This medicine is used on its own to treat adult patients with a specific type of cancer of the lung (non-small cell lung cancer):

- that is identified by a change (mutation) in the gene for EGFR. Webrix can be prescribed to you as your first treatment or if prior chemotherapy treatment has been insufficient.
- of squamous type if prior chemotherapy treatment has been insufficient.

How does Webrix work?

Webrix is a medicine which contains the active substance afatinib. It works by blocking the activity of a group of proteins called the ErbB family (including EGFR [epidermal growth factor receptor or ErbB1], HER2 [ErbB2], ErbB3 and ErbB4). These proteins are involved in the growth and spread of cancer cells and can be affected by changes (mutations) in the genes that produce them. By blocking the activity of these proteins this medicine can inhibit growth and spread of cancer cells.

How is Webrix used?

The pharmaceutical form is film-coated 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 in Sweden.

What benefits of Webrix have been shown in studies?

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

What are the possible side effects from Webrix?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Webrix approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for GIOTRIF, 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 Webrix?

A risk management plan has been developed to ensure that the product 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, 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.

For more details, please see the full PAR for Webrix on the following website: MRI - Home.

Other information about Webrix

The full PAR for Webrix can be found on the following website: MRI - Home. For more information about treatment with Webrix, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-05.