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EPAR summary for the public

Giotrif

afatinib

This is a summary of the European public assessment report (EPAR) for Giotrif. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Giotrif.

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

What is Giotrif and what is it used for?

Giotrif is a medicine used to treat a type of lung cancer known as non-small cell lung cancer. It is used specifically in adults with advanced cancer in the following situations:

- when the cancer has a mutation in the gene for a protein called EGFR and has not been previously treated with tyrosine kinase inhibitor medicines.
- when the cancer is of a squamous cell type (from cells of the lining of the lungs) and has worsened despite treatment with platinum-based chemotherapy.

Giotrif contains the active substance afatinib.

How is Giotrif used?

Treatment with Giotrif should be started and supervised by a doctor experienced in the use of cancer medicines.

Giotrif is available as tablets (20, 30, 40 and 50 mg) and is only available with a prescription. The recommended dose is 40 mg once daily but this may be increased to up to 50 mg per day in patients who tolerate the 40 mg dose, or interrupted and reduced in patients experiencing side effects. Treatment should continue for as long as possible, until the disease worsens or the side effects become too severe.

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The tablets should be taken without food and no food should be eaten for at least 3 hours before and 1 hour after taking the tablets.

How does Giotrif work?

The active substance in Giotrif, afatinib, is an ErbB family blocker. This means that it blocks the action of a group of proteins known as 'ErbB family' which are found on the surface of cancer cells and are involved in stimulating the cells to divide. By blocking these proteins, afatinib helps to control cell division and thereby slows down the growth and spread of the non-small cell lung cancer.

EGFR proteins are part of the ErbB family. Lung cancer cells with mutated EGFR proteins are particularly sensitive to afatinib.

What benefits of Giotrif have been shown in studies?

Giotrif has been shown to significantly delay disease progression in patients with non-small cell lung cancer.

In a main study in 345 patients with tumours that have mutated EGFR genes, patients treated with Giotrif lived on average for 11 months without their disease getting worse compared with 7 months for patients who were treated with two other cancer medicines, pemetrexed and cisplatin.

In a second study in 795 patients with the squamous cell cancer type, patients treated with Giotrif lived on average for 2.6 months without their disease worsening compared with 1.9 months for patients treated with another cancer medicine, erlotinib.

What are the risks associated with Giotrif?

The most common side effects with Giotrif (which may affect more than 1 in 10 people) are paronychia (nail bed infection), reduced appetite, epistaxis (nosebleeds), diarrhoea, nausea (feeling sick), vomiting, stomatitis (inflammation of the lining of the mouth), rash, acneiform dermatitis (acne-like skin conditions), pruritus (itching), and dry skin. For the full list of all side effects and restrictions with Giotrif, see the package leaflet.

Why is Giotrif approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that the benefits of Giotrif outweigh its risks and recommended that it be granted marketing authorisation in the EU. The CHMP considered that in patients treated with Giotrif the improvement in progression-free survival (how long they lived without the disease getting worse) was a meaningful benefit for patients. In addition, the side effects of the medicine were considered to be manageable and similar to those seen with medicines of the same class.

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

A risk management plan has been developed to ensure that Giotrif 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 Giotrif, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Giotrif

The European Commission granted a marketing authorisation valid throughout the European Union for Giotrif on 25 September 2013.

The full EPAR for Giotrif can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Giotrif, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.