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Afinitor (*everolimus*)

An overview of Afinitor and why it is authorised in the EU

What is Afinitor and what is it used for?

Afinitor is a cancer medicine used to treat the following cancers:

- breast cancer that is advanced (has started to spread) in women who have been through their menopause. Afinitor is used in breast cancer that is 'hormone receptor-positive' (when the cancer cells have oestrogen receptors on their surface) and 'HER2/neu negative' (when the cancer cells do not contain high levels of the HER2/neu [human epidermal growth factor receptor-2] protein). Afinitor is used together with a medicine called exemestane after other treatments called 'non-steroidal aromatase inhibitors' have not worked;
- pancreatic neuroendocrine tumours (tumours of the hormone-producing cells in the pancreas) when the cancer cells are well- or moderately differentiated (which means that they can be distinguished from normal pancreas cells). It is used when the cancer is metastatic (has spread to other parts of the body) or when it cannot be surgically removed;
- neuroendocrine tumours originating in the lungs or gut, when the cancer cells are well-differentiated and the cancer is metastatic or cannot be removed by surgery.
- advanced renal cell carcinoma (a kidney cancer), when the cancer has worsened despite treatment with a 'VEGF-targeted' medicine (a type of medicine that blocks the effects of vascular endothelial growth factor proteins).

Afinitor contains the active substance everolimus.

How is Afinitor used?

Afinitor can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the use of cancer treatments.

Afinitor is available as tablets (2.5, 5 and 10 mg) and the recommended dose is 10 mg once a day. Treatment should continue for as long as it works or until side effects become unacceptable. The doctor may reduce the dose or stop treatment for a short period if the patient has severe or intolerable side effects. Doses need to be reduced for patients with liver problems.

The tablets should be taken at the same time every day and consistently with or without food.

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For more information about using Afinitor, see the package leaflet or contact your doctor or pharmacist.

How does Afinitor work?

The active substance in Afinitor, everolimus, blocks an enzyme called 'mammalian target of rapamycin' (mTOR). In the body, everolimus first attaches to a protein called FKBP-12 that is found inside cells to make a 'complex'. This complex then blocks mTOR. Since mTOR is involved in the control of cell division and the growth of blood vessels, Afinitor prevents the division of cancer cells and reduces their blood supply. This slows down the growth and spread of the cancer.

What benefits of Afinitor have been shown in studies?

Breast cancer

Afinitor in combination with exemestane has been studied in 724 patients with hormone receptor-positive and HER2/neu-negative advanced breast cancer which had got worse after treatment with letrozole and anastrazole (non-steroidal aromatase inhibitors). Patients who took Afinitor lived for an average of 7.8 months without their disease getting worse, compared with 3.2 months for the patients who took placebo (a dummy treatment).

Pancreatic neuroendocrine tumours

A study in 410 patients with advanced well- or moderately differentiated neuroendocrine tumours of pancreatic origin compared Afinitor with placebo. Patients who took Afinitor lived for an average of 11.0 months without the disease getting worse, compared with 4.6 months for the patients who took placebo.

Neuroendocrine tumours originating in the lung or gut

Afinitor was studied in 302 patients with advanced neuroendocrine tumours of lung or gut origin. Patients who received Afinitor and best supportive treatments lived for an average of 11 months without the disease getting worse compared with around 4 months for patients who received placebo and best supportive treatments to relieve disease symptoms.

Renal cell carcinoma

Afinitor was studied in 416 patients with advanced renal cell carcinoma that had got worse despite treatment with VEGF-targeted medicines (sunitinib, sorafenib or both). Patients who took Afinitor lived for an average of 4.9 months without the disease getting worse, compared with 1.9 months for the patients who took placebo.

What are the risks associated with Afinitor?

The most common side effects with Afinitor (which may affect more than 1 in 10 people) are rash, itching, nausea, decreased appetite, dysgeusia (taste disturbances), headache, weight loss, peripheral oedema (swelling, especially of the ankles and feet), cough, anaemia (low red blood cell counts), tiredness, diarrhoea, weakness, infections, stomatitis (inflammation of the lining of the mouth), hyperglycaemia (high blood glucose levels), hypercholesterolaemia (high blood cholesterol levels), pneumonitis (inflammation of the lungs) and nosebleeds. For the full list of side effects of Afinitor, see the package leaflet.

Afinitor must not be used in people who are hypersensitive (allergic) to other rapamycin derivatives (substances with a similar structure to everolimus) or to any of the other ingredients. For the full list of restrictions, see the package leaflet.

Why is Afinitor authorised in the EU?

The European Medicines Agency decided that Afinitor's benefits are greater than its risks and it can be authorised for use in the EU. Afinitor slowed down disease progression in patients with advanced neuroendocrine tumours of pancreatic origin, advanced renal cell carcinoma and hormone-receptor-positive advanced breast cancer. The Agency also concluded that the 7-month delay in disease progression for patients with neuroendocrine tumours originating in the lungs or gut was valuable, despite the known side effects of Afinitor.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Afinitor have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Afinitor are continuously monitored. Side effects reported with Afinitor are carefully evaluated and any necessary action taken to protect patients.

Other information about Afinitor

Afinitor received a marketing authorisation valid throughout the EU on 03 August 2009.

Further information on Afinitor can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Afinitor.

This overview was last updated in 11-2018.