EMA/89209/2019
EMEA/H/C/004779

Vizimpro (*dacomitinib*)

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

What is Vizimpro and what is it used for?

Vizimpro is a cancer medicine used to treat adults with non-small cell lung cancer (NSCLC) when the disease is advanced or has spread.

Vizimpro is used on its own and only in patients with certain mutations (changes) in the gene for a protein called epidermal growth factor receptor (EGFR).

Vizimpro contains the active substance dacomitinib.

How is Vizimpro used?

Vizimpro is available as tablets (15, 30 and 45 mg). The patient should normally take a 45-mg tablet once a day, at around the same time every day, for as long as they benefit from it and the side effects are tolerable. If certain side effects develop the doctor may decide to reduce the dose or stop treatment.

Vizimpro can only be obtained with a prescription and treatment must be started and supervised by a doctor with experience in using cancer medicines. Before starting treatment, the presence of mutations in the *EGFR* gene should be confirmed by appropriate tests.

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

How does Vizimpro work?

The active substance in Vizimpro, dacomitinib, belongs to a group of cancer medicine called tyrosine kinase inhibitor. It blocks the activity of EGFR, which normally controls growth and division of cells. In lung cancer cells, EGFR is often overactive, causing uncontrolled growth of cancer cells. By blocking EGFR, dacomitinib helps to reduce the growth and spread of the cancer.

What benefits of Vizimpro have been shown in studies?

Vizimpro has been shown to be more effective than gefitinib (another medicine for non-small cell lung cancer) at prolonging the time patients lived without their disease getting worse. In one main study

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involving 452 patients with EGFR mutations, patients given Vizimpro lived on average for around 15 months without their disease getting worse, compared with 9 months for those given gefitinib.

What are the risks associated with Vizimpro?

The most common side effects with Vizimpro (which may affect more than 1 in 5 people) are diarrhoea, rash, stomatitis (inflammation of the lining of the mouth), nail disorder, dry skin, loss of appetite, conjunctivitis (redness and discomfort in the eye), weight and hair loss, itching, elevated levels of transaminases (a sign of liver problems) and nausea (feeling sick). The most frequent serious side effects are diarrhoea, interstitial lung disease (disorders causing scarring in the lungs), rash and loss of appetite.

For the full list of side effects and restrictions of Vizimpro, see the package leaflet.

Why is Vizimpro authorised in the EU?

Vizimpro was shown to significantly improve the length of time patients lived without their disease getting worse. Patients taking Vizimpro lived for an extra 6 months without their disease getting worse compared with those taking gefitinib. Although Vizimpro caused more side effects than gefitinib, these were considered manageable. The European Medicines Agency therefore decided that Vizimpro's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Vizimpro

Vizimpro received a marketing authorisation valid throughout the EU on 2 April 2019.

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

This overview was last updated in 05-2019.