EMA/191270/2022
EMEA/H/C/004302

Verzenios (*abemaciclib*)

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

What is Verzenios and what is it used for?

Verzenios is a cancer medicine used to treat women with breast cancer that is advanced or has spread to other parts of the body (metastatic). It is also used to treat men and women with early breast cancer after surgery where the cancer has spread to the lymph nodes (node-positive) and display other features indicating a higher risk for the cancer to come back. Verzenios can only be used when the cancer cells have certain types of receptor (called hormone receptors) on their surface (HR-positive) and do not produce abnormally large quantities of another receptor called HER2 (HER2-negative).

It is used together with a hormonal medicine, such as tamoxifen, an aromatase inhibitor or fulvestrant.

In women who have not yet reached menopause, a medicine called a luteinising hormone-releasing hormone agonist should also be given.

Verzenios contains the active substance abemaciclib.

How is Verzenios used?

Verzenios can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Verzenios is available as tablets. The recommended dose is 150 mg twice a day. In patients with early breast cancer, treatment should last for two years. In women with metastatic breast cancer, treatment should continue for as long as the patient is benefitting from it and side effects are tolerable. If the patient experiences certain side effects, treatment may need to be interrupted or stopped, or the dose reduced. The dose should be reduced if the patient is also taking certain medicines called 'CYP3A4 inhibitors'. Grapefruit juice should be avoided during treatment with Verzenios as it may affect the way the medicine is absorbed and broken down in the body.

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

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How does Verzenios work?

The active substance in Verzenios, abemaciclib, blocks the activity of enzymes known as cyclin-dependent kinases (CDK) 4 and 6, which play a key role in regulating the way cells grow and divide. In some cancers, including HR-positive breast cancer, the activity of CDK4 and CDK6 is increased, which helps the cancer cells to multiply uncontrollably. By blocking CDK4 and CDK6, Verzenios slows the growth of HR-positive breast cancer cells.

What benefits of Verzenios have been shown in studies?

Early breast cancer

One main study, involving over 5,100 patients over the age of 18, with HR-positive, HER2-negative, node-positive high risk early breast cancer showed that Verzenios can prolong the time patients live without their disease coming back (recurrence) when combined with hormonal treatment (tamoxifen or aromatase inhibitor).

After a study period of around 2 years, 8.5% (218/2,555) of patients taking Verzenios in combination with hormonal treatment experienced recurrence of disease in the form of spreading elsewhere in the body or locally invasive disease (invasive disease-free survival), compared to 12.4% (318/2565) of patients taking hormonal treatment only.

Advanced breast cancer

Two main studies, involving 1,162 women, mostly postmenopausal, with HR-positive, HER2-negative breast cancer that had started to spread, showed that Verzenios can prolong the time patients live without their disease getting worse (progression-free survival).

In the first study women taking Verzenios and an aromatase inhibitor (letrozole or anastrozole) lived on average 28 months without their disease getting worse compared with 15 months for women taking placebo (a dummy treatment) and an aromatase inhibitor.

In the second study women taking Verzenios and fulvestrant lived on average 16 months without their disease getting worse, compared with 9 months for women taking placebo and fulvestrant.A third study, conducted in 132 women who had received previous cancer treatment, failed to demonstrate that Verzenios used on its own was of benefit in the treatment of HR-positive, HER2-negative breast cancer that had started to spread.

What are the risks associated with Verzenios?

The most common side effects with Verzenios (which may affect more than 1 in 10 people) are diarrhoea, infections, neutropenia (low levels of neutrophils, a type of white blood cell), leucopenia (low white blood cell counts), anaemia (low red blood cell counts), tiredness, nausea (feeling sick), vomiting, hair loss and decreased appetite.

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

Why is Verzenios authorised in the EU?

The European Medicines Agency decided that the benefits of Verzenios are greater than its risks and it can be authorised for use in the EU. Verzenios used with an aromatase inhibitor or fulvestrant increased the time it took for the disease to get worse in postmenopausal women with HR-positive and HER2-negative breast cancer that is advanced or metastatic. Data were considered sufficient to conclude that Verzenios can be of benefit also in women who have not yet been through the

menopause. Verzenios has also shown to improve outcome in patients with early breast cancer, when used in combination with hormonal therapy. The Agency considered that, despite the side effects of Verzenios, the overall safety profile was acceptable.

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

The company that markets Verzenios will submit the results of an ongoing study on the long-term effectiveness and safety of the medicine in combination with hormonal medicines for the treatment of HR-positive, HER2-negative, node-positive early breast cancer, which has a high risk of recurrence.

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

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

Other information about Verzenios

Verzenios received a marketing authorisation valid throughout the EU on 27 September 2018.

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

This overview was last updated in 03-2022.