EMA/521639/2018
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. 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, either 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 (50 mg, 100 mg and 150 mg). The recommended dose is 150 mg twice a day. 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.

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 CDK 4 and 6 is increased, which

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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?

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), anaemia (low red blood cell counts), tiredness, nausea (feeling sick), vomiting 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. Regarding safety, the main risk is diarrhoea, which is considered manageable with dose reduction.

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

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/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 10-2018.