



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Piqray (*alpelisib*)

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

### What is Piqray and what is it used for?

Piqray is a cancer medicine used to treat postmenopausal women and men with breast cancer that is locally advanced or has spread to other parts of the body.

Piqray can only be used when the cancer cells have receptors for certain hormones on their surface (HR-positive) and do not have large quantities of another receptor called HER2 (HER2-negative). The cancer cells must also have been shown to have a specific mutation (change) in the gene called 'PIK3CA'. Piqray is used with the medicine fulvestrant (hormone treatment for breast cancer) after hormone treatment used alone has failed.

Piqray contains the active substance alpelisib.

### How is Piqray used?

Piqray can only be obtained with a prescription and should be started by a doctor experienced in using cancer medicines.

Piqray is available as tablets to take by mouth immediately after food. The recommended dose is 300 mg once a day at about the same time each day, and treatment should continue for as long as the patient benefits from it. If the patient has unacceptable side effects, the doctor may stop treatment or reduce the dose.

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

### How does Piqray work?

In patients whose cancer cells have a PIK3CA mutation, an abnormal form of the enzyme PI3K is produced that stimulates cancer cells to divide and grow in an uncontrolled fashion. The active substance in Piqray, alpelisib, works by blocking the activity of the abnormal PI3K, thereby reducing the growth and spread of the cancer.

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## **What benefits of Piqray have been shown in studies?**

A main study involved 340 patients with advanced breast cancer with a PIK3CA mutation in whom hormone treatment had not worked or the cancer had come back. Patients treated with Piqray in combination with fulvestrant lived on average for 11 months without their disease getting worse compared with around 6 months for patients who received placebo (a dummy treatment) with fulvestrant.

## **What are the risks associated with Piqray**

The most common side effects with Piqray (which may affect more than 1 in 5 people) are increased blood sugar which may require treatment (less frequently, reduced blood sugar), increased levels of creatinine (which may indicate kidney problems), stomatitis (inflammation of the lining of the mouth), nausea, vomiting, diarrhoea, decreased appetite and weight loss, abnormal blood tests for liver function, increased blood levels of lipase (which may indicate inflammation of the pancreas), rash, reduced levels of lymphocytes (a type of white blood cell), anaemia (reduced red blood cells), tiredness, hypocalcaemia (low blood levels of calcium), prolonged blood clotting time and hair loss.

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

## **Why is Piqray authorised in the EU?**

The European Medicines Agency decided that Piqray's benefits are greater than its risks and it can be authorised for use in the EU. Piqray used with fulvestrant increased the time before the disease got worse in patients with HR-positive and HER2-negative breast cancer that is advanced or has spread. In terms of the medicine's side effects, the main concern is high blood sugar levels which may lead to diabetes and gut problems but the Agency has recommended measures to manage this.

## **What measures are being taken to ensure the safe and effective use of Piqray?**

The company that markets Piqray will carry out a study to investigate its effectiveness and long-term safety. The company will also provide information on the medicine for healthcare professionals, including information on high blood sugar levels and how to manage them.

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

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

## **Other information about Piqray**

Piqray received a marketing authorisation valid throughout the EU on 27 July 2020.

Further information on Piqray can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/piqray](https://ema.europa.eu/medicines/human/EPAR/piqray).

This overview was last updated in 07-2020.