

Public Summary SwissPAR dated 20.10.2020

Piqray[®] (active substance: alpelisib)

First authorisation in Switzerland: 24.03.2020

Medicine (film-coated tablets) for the treatment of postmenopausal women with advanced breast cancer

About the medicine

The medicine Piqray with the active substance alpelisib is a cancer medicine used to treat postmenopausal women with advanced breast cancer. It is used in combination with the medicine fulvestrant (hormone treatment for cancer) after hormone treatment on its own has failed.

Treatment with Piqray is considered as an option only if the cancer cells are able to bind to certain hormones due to a receptor

(HR-positive) and if large quantities of another receptor called HER2 are not present (HER2-negative). Furthermore, the gene called PIK3CA must be mutated in a particular way in the patients.

In order to establish whether a treatment with Piqray is appropriate, a blood and/or tissue test is carried out before the start of treatment.

Mode of action

An enzyme named PI3K (phosphatidylinositol-3-kinase) stimulates the cancer cells to grow and replicate. Piqray blocks the effect

of this enzyme and thereby delays the growth of the cancer cells, killing them and preventing the formation of new cancer cells.

Use

Piqray with the active substance alpelisib is a prescription-only medicine. The treatment with Piqray must be initiated by a doctor with experience in cancer treatment. Piqray is available as a film-coated tablet in dosage strengths of 50 mg, 150 mg and 200 mg. The usual starting dose is 300 mg once daily,

taken immediately after a meal and always at the same time.

Piqray can affect the blood sugar level. The blood sugar level must be checked at regular intervals during treatment. Patients who have previously suffered severe skin reactions may not be treated with Piqray.

Efficacy

The efficacy of Piqray with the active substance alpelisib has been investigated in a study with 571 female patients and 1 male patient. One group of female and male patients received Piqray in combination with fulvestrant. The other group received a dummy treatment (placebo) in combination with fulvestrant. The results of the study showed that female and male patients who

received the Piqray in combination with fulvestrant survived for longer without disease progression compared to those female and male patients who received a placebo in combination with fulvestrant.

Since only one male patient was included in the study investigating the efficacy of Piqray, the indication is restricted to female patients until further data on male patients are available.

Precautions, undesirable effects & risks

Piqray may not be used in those who are hypersensitive to the active substance or any of the excipients.

An elevated blood sugar level is a common and serious risk associated with the treatment with Piqray. Patients should be advised of the signs of severe skin reactions such as fever, flu-like symptoms, mucosal lesions or progressive skin rash.

Other common adverse drug reactions are diarrhoea, nausea and vomiting, fatigue, weakness and loss of strength, decreased appetite, inflammation of the lining of the mouth and weight loss.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

The study showed that female and male patients who received the Piqray in combination with fulvestrant survived for longer without worsening of the disease compared to those female and male patients who received a placebo in combination with fulvestrant.

Taking all the risks and precautions into account, and based on the available data, the benefits of Piqray outweigh the risks. Swissmedic has therefore authorised the medicine Piqray with the active substance alpelisib for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals:
[Information for healthcare professionals Piqray®](#)

Information for patients (package leaflet):
[Information for patients Piqray®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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