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Vanflyta (*quizartinib*)

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

What is Vanflyta and what is it used for?

Vanflyta is a cancer medicine used to treat adults who have been newly diagnosed with acute myeloid leukaemia (AML), a cancer of the white blood cells. It is only given to those patients whose cancer cells have a particular change (mutation) known as ITD in the gene for a protein called FLT3.

Vanflyta is used together with cytarabine and anthracycline (other cancer medicines, also called chemotherapy) at induction (start of treatment) . After induction it is used in combination with cytarabine alone (consolidation). It is then used on its own as maintenance therapy.

Vanflyta contains the active substance quizartinib.

How is Vanflyta used?

Vanflyta can only be obtained with a prescription and treatment should be started by a doctor experienced in using cancer treatments.

Before taking Vanflyta, the patient must have a test to confirm that their cancer cells have the ITD mutation in the *FLT3* gene (ITD-FLT3 positive).

Vanflyta is available as tablets to be taken by mouth. It is taken once a day for two weeks during each 4-week chemotherapy cycle. After chemotherapy is complete, Vanflyta is taken once a day on its own as maintenance treatment. Treatment can continue for up to 36 cycles lasting 4 weeks each.

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

How does Vanflyta work?

The active substance in Vanflyta, quizartinib, blocks the action of enzymes known as tyrosine kinases, in particular a tyrosine kinase called FLT3 that normally controls growth and division of white blood cells. In patients who have an *FLT3* mutation, the FLT3 enzyme is overactive and stimulates the growth of too many white blood cells. By blocking FLT3, quizartinib is expected to stop the growth of white blood cells and thus slow down the development of the cancer.

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What benefits of Vanflyta have been shown in studies?

A main study involving 539 patients newly diagnosed with AML compared Vanflyta with placebo (a dummy treatment). Patients were given Vanflyta or placebo in combination with chemotherapy. Those whose cancer responded to treatment either continued their treatment without chemotherapy or had a blood stem cell transplant before continuing their treatment. After three years of treatment, 50% of patients who received Vanflyta were still alive compared with 41% of those who received placebo.

What are the risks associated with Vanflyta?

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

The most common side effects with Vanflyta (which may affect more than 1 in 5 people) include increased levels of an enzyme in the blood called alanine aminotransferase, decreased levels of blood platelets, decreased levels of haemoglobin (the protein in red blood cells that carries oxygen around the body), diarrhoea, nausea (feeling sick), abdominal (belly) pain, headache, vomiting and decreased levels of neutrophils (a type of white blood cell).

The most common serious side effect with Vanflyta (which may affect up more than 1 in 10 people) is neutropenia (low levels of neutrophils). Other common serious side effects (which may affect up to 1 in 10 people) include fungal infections and herpes infections.

The most common serious side effects with Vanflyta (which may affect up to 1 in 10 people) that led to dose reduction or interruption include neutropenia, thrombocytopenia (low levels of blood platelets) and prolonged QT interval (abnormal electrical activity of the heart that affects its rhythm).

Vanflyta should not be used by patients who are breast-feeding or who have congenital long QT syndrome (abnormal electrical activity of the heart caused by a gene defect).

Why is Vanflyta authorised in the EU?

When used in combination with chemotherapy, Vanflyta has been shown to prolong the lives of people newly diagnosed with ITD-FLT3-positive AML. Although some of the medicine's side effects can be serious, the Agency considered that adequate measures were in place to manage or minimise the risks with Vanflyta.

The European Medicines Agency therefore decided that Vanflyta'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 Vanflyta?

The company that markets Vanflyta will provide educational materials for healthcare professionals and patients on how to minimise the risk of prolonged QT interval and recognise signs and symptoms of this side effect.

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

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

Other information about Vanflyta

Vanflyta received a marketing authorisation valid throughout the EU on 6 November 2023.

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

This overview was last updated in 11-2023.