Package leaflet: Information for the patient

VANFLYTA 17.7 mg film-coated tablets
VANFLYTA 26.5 mg film-coated tablets
quizartinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What VANFLYTA is and what it is used for

What VANFLYTA is
VANFLYTA contains the active substance quizartinib. It is a type of cancer medicine called a ‘protein kinase inhibitor’. The medicine is used along with chemotherapy to treat adults who have acute myeloid leukaemia (AML, a type of blood cancer), with a mutation (change) in the FLT3 gene called ‘FLT3-ITD’. VANFLYTA treatment may be continued also after a bone marrow transplant when patients have sufficiently recovered.

Your doctor will test your cancer cells for changes in the FLT3 gene to look for FLT3-ITD mutations beforehand to make sure that VANFLYTA is right for you.

How VANFLYTA works
In AML, the body makes a large amount of abnormal white blood cells that do not mature to become healthy cells. VANFLYTA works by blocking the action of proteins called ‘tyrosine kinases’ in these abnormal cells. This slows down or stops the abnormal cells from dividing and growing uncontrollably, and helps immature cells grow into normal cells.

2. What you need to know before you take VANFLYTA

Do not take VANFLYTA
- if you are allergic to quizartinib or any of the other ingredients in this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice.
- if you were born with a heart problem called ‘long QT syndrome’ (abnormal electrical activity of the heart that affects its rhythm).
- if you are breast-feeding (see ‘Pregnancy, breast-feeding and fertility’).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking VANFLYTA:
- if you have or have had any heart problems including arrhythmia (abnormal heart rhythm), myocardial infarction (heart attack) within 6 months, congestive heart failure (heart isn't pumping hard enough), uncontrolled angina pectoris (chest pain) or uncontrolled hypertension (blood pressure that's too high).
- if you have been told you have low blood levels of potassium or magnesium.
- if you are taking medicines that can prolong the QT interval (irregular heart rhythm; see 'Other medicines and VANFLYTA').
- if you are taking strong CYP3A inhibitors (see 'Other medicines and VANFLYTA').
- if you have or have had fever, cough, chest pain, shortness of breath, tiredness or pain when urinating.

Monitoring during treatment with VANFLYTA
Blood tests
Your doctor will perform regular blood tests during treatment with VANFLYTA to check your blood cells (white blood cells, red blood cells, and platelets) and electrolytes (salts such as sodium, potassium, magnesium, calcium, chloride and bicarbonate in blood). Your doctor will check your electrolytes more often if you are experiencing diarrhoea or vomiting.

Electrocardiogram
Before and during your treatment, your doctor will check your heart with an electrocardiogram (ECG) to make sure your heart is beating normally. ECGs will be done weekly initially and less often thereafter as decided by your doctor. Your doctor will check your heart more often if you are taking other medicines that prolong the QT interval (see 'Other medicines and VANFLYTA').

Infections in patients older than 65 years
Elderly patients are at increased risk for very serious infections when compared to younger patients, especially in the early treatment period. If you are older than 65 years of age you will be closely monitored for the occurrence of severe infections during induction.

Children and adolescents
Do not give this medicine to children or adolescents below 18 years of age because there is not enough information about its use in this age group.

Other medicines and VANFLYTA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, vitamins, antacids (medicines for heartburn and stomach acidity) and herbal supplements. This is because some medicines can affect how VANFLYTA works.

In particular, the following medicines may increase the risk of side effects with VANFLYTA by increasing the levels of this medicine in the blood:
- certain medicines used to treat fungal infections – such as itraconazole, posaconazole or voriconazole;
- certain antibiotics – such as clarithromycin or telithromycin;
- nefazodone, a medicine used to treat major depression.

The following medicines may reduce the effectiveness of VANFLYTA:
- certain medicines used to treat tuberculosis – such as rifampicin;
- certain medicines used to treat seizures or epilepsy – such as carbamazepine, primidone, phenobarbital or phenytoin;
- certain medicines to treat prostatic cancer – such as apalutamide and enzalutamide;
- mitotane – a medicine used for the treatment of symptoms of tumours of the adrenal glands;

- bosentan – a medicine used to treat high blood pressure in the lungs (pulmonary arterial hypertension);
- St. John's Wort (*Hypericum perforatum*) – an herbal product used for anxiety and mild depression.

Certain medicines use to treat HIV may either increase the risk of side effects (e.g., ritonavir) or reduce the effectiveness (e.g., efavirenz or etravirine) of VANFLYTA.

QT interval prolonging medicinal products
Co-administration of VANFLYTA with other medicinal products that prolong the QT interval may further increase the risk of QT prolongation. Examples of QT prolonging medicinal products include but are not limited to antifungal azoles, ondansetron, granisetron, azithromycin, pentamidine, doxycycline, moxifloxacin, atovaquone, prochlorperazine and tacrolimus.

Pregnancy, breast-feeding and fertility

Pregnancy

You should not take VANFLYTA during pregnancy. This is because it may harm your unborn baby. Women who are able to become pregnant should have a pregnancy test within 7 days before taking this medicine.

Women should use effective contraception during treatment with VANFLYTA and for at least 7 months after stopping treatment. Men should use effective contraception during treatment with VANFLYTA and for at least 4 months after stopping treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Breast-feeding

Do not breast-feed during treatment with VANFLYTA, and for at least 5 weeks after stopping treatment. This is because it is not known if VANFLYTA passes into your breast milk (see 'Do not take VANFLYTA'**)**.
If you are breast-feeding, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Fertility

VANFLYTA may reduce fertility in women and men. You should discuss this with your doctor before starting treatment.

Driving and using machines
VANFLYTA is unlikely to affect your ability to drive or use machines.

3. How to take VANFLYTA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much VANFLYTA to take
Your doctor or pharmacist will tell you exactly how much VANFLYTA to take. Do not change your dose or stop taking VANFLYTA without talking to your doctor first.

Usually you will start by taking 35.4 mg (two 17.7 mg tablets) once daily for 2 weeks during each cycle of chemotherapy. The maximum recommended dose is 53 mg once daily.

Your doctor may start you on a lower dose of one 17.7 mg tablet once daily if you are taking certain other medicines.

After your chemotherapy is completed your doctor may change your dose to one 26.5 mg tablet once daily for 2 weeks and then increase your dose to 53 mg (two 26.5 mg tablets) once daily going forward depending on how you respond to VANFLYTA.

Your doctor may temporarily interrupt treatment or change your dose based on blood tests, side effects or other medicines you may be taking.

Your doctor will discontinue your treatment if you are having a stem cell transplant. Your doctor will tell you when to stop taking your medicine and when to restart it.

Taking this medicine
- Take VANFLYTA by mouth - either with or without food.
- Take VANFLYTA at about the same time each day. This will help you remember to take your medicine.
- If you vomit after you take this medicine, do not take any more tablets until your next scheduled dose.

How long to take VANFLYTA
Continue taking VANFLYTA for as long as your doctor tells you. Your doctor will regularly monitor your condition to check that the treatment is continuing to work.

If you have any questions about how long to take VANFLYTA, talk to your doctor or pharmacist.

If you take more VANFLYTA than you should
If you accidentally take more tablets than you should, or if someone else accidentally takes your medicine, talk to a doctor straightaway or go to a hospital and take this package leaflet with you. Medical treatment may be necessary.

If you forget to take VANFLYTA
If you forget to take VANFLYTA, take it as soon as possible on the same day. Take your next dose at your usual time on the next day.

Do not take an extra dose (two doses on the same day) to make up for a forgotten dose.

If you stop taking VANFLYTA
Stopping your treatment with VANFLYTA may cause your condition to become worse. Do not stop taking your medicine unless your doctor tells you to do so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor, pharmacist or nurse immediately if you notice the following side effects:
- feeling dizzy, lightheaded or faint. These could be signs of a heart problem called ‘prolonged QT interval’ (abnormal electrical activity of the heart that affects its rhythm).
- fever, cough, chest pain, shortness of breath, tiredness or pain when urinating. These could be signs of an infection or febrile neutropenia (low white blood cell counts with fever).

Very common side effects
(may affect more than 1 in 10 people)
- increase in alanine aminotransferase (abnormal liver enzyme results)
- thrombocytopenia (low levels of blood platelets)
- anaemia (low levels of red blood cells)
- neutropenia (low levels of neutrophils, a type of white blood cell)
- diarrhoea
- nausea (feeling sick)
- abdominal (stomach) pain
- headache
- vomiting
- oedema (swelling of the face, arms and legs)
- upper respiratory tract infections (nose and throat infections)
- decreased appetite
- epistaxis (severe nosebleeds)
- fungal infections
- herpes infections
- dyspepsia (indigestion)
- bacteraemia (bacteria in the blood)

Common side effects
(may affect up to 1 in 10 people)
- pancytopenia (low levels in all types of blood cells)

Uncommon side effects
(may affect up to 1 in 100 people)
- cardiac arrest (heart stops beating)
- ventricular fibrillation (dangerous, irregular and uncoordinated contractions of the lower chambers of the heart)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VANFLYTA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What VANFLYTA contains

- The active substance is quizartinib.
  VANFLYTA 17.7 mg: Each film-coated tablet contains 17.7 mg quizartinib (as dihydrochloride).
  VANFLYTA 26.5 mg: Each film-coated tablet contains 26.5 mg quizartinib (as dihydrochloride).
- The other ingredients are:
  VANFLYTA 17.7 mg:
  Tablet core: Hydroxypropylbetadex, microcrystalline cellulose, magnesium stearate
  Film-coating: Hypromellose, talc, triacetin, titanium dioxide
  VANFLYTA 26.5 mg:
  Tablet core: Hydroxypropylbetadex, microcrystalline cellulose, magnesium stearate
  Film-coating: Hypromellose, talc, triacetin, titanium dioxide, yellow iron oxide

What VANFLYTA looks like and contents of the pack

VANFLYTA 17.7 mg film-coated tablets (tablets) are white, round and with 'DSC 511' on one side, and available in cartons containing 14 x 1 or 28 x 1 film-coated tablets in aluminium/aluminium perforated unit dose blisters.

VANFLYTA 26.5 mg film-coated tablets (tablets) are yellow, round and with 'DSC 512' on one side, and available in cartons containing 14 x 1, 28 x 1 or 56 x 1 film-coated tablets in aluminium/aluminium perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
United Kingdom (Northern Ireland)
Daiichi Sankyo Europe GmbH
Zielstattstrasse 48
81379 Munich
Germany

United Kingdom (Great Britain)
Daiichi Sankyo UK Ltd
Building 4
Uxbridge Business Park
Sanderson Road
Uxbridge
UB8 1DH

Manufacturer
Daiichi Sankyo Europe GmbH
Luitpoldstrasse 1
85276 Pfaffenhofen
Germany

For any information about this medicine, please contact:
United Kingdom (Northern Ireland)
Daiichi Sankyo Europe GmbH., Tel: +49 (0) 89 7808 0

United Kingdom (Great Britain)
Daiichi Sankyo UK Ltd., Tel: +44 (0) 800 028 5122

This leaflet was last revised in September 2023.

United Kingdom (Northern Ireland)
Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu

vanflyta-pil-gb-v01-2403