EMA/530349/2023
EMEA/H/C/005885

Finlee (*dabrafenib*)

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

What is Finlee and what is it used for?

Finlee is a cancer medicine used to treat children aged 1 year and older with glioma (a type of brain tumour). It is used together with another cancer medicine, trametinib. Finlee is only used in patients whose glioma cancer cells have a specific mutation (change) in the BRAF gene called 'BRAF V600E'.

Finlee can be used in children with:

- low-grade glioma who require systemic therapy;
- high-grade glioma when the patient has received at least one prior radiation or chemotherapy treatment.

Glioma is rare, and Finlee was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 December 2020. Further information on the orphan designation can be found on the EMA website.

Finlee contains the active substance dabrafenib.

How is Finlee used?

The medicine can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in treating cancer. Before starting treatment, patients must have a test to confirm their cancer cells have BRAF V600E mutation.

Finlee is available as dispersible tablets to be taken twice a day. The tablets should be dispersed (mixed) in a small amount of water before being taken. Finlee is used together with trametinib powder for oral solution (to make up a drinkable liquid), which should be given once a day together with one of the two daily doses of Finlee.

Treatment with Finlee should continue as long as the patient benefits from it. In case of side effects the doctor may reduce or stop the treatment.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Finlee work?

Glioma tumour cells with the BRAF mutation produce an abnormal form of a protein called BRAF. The abnormal BRAF protein activates another protein called MEK that is involved in stimulating cell division, resulting in uncontrolled division of cells and thus development of cancer. The active substance in Finlee, dabrafenib, works by blocking the action of the abnormal BRAF protein in patients with the BRAF mutation and thereby helps slow down the growth and spread of the cancer. The most commonly observed BRAF mutation is V600E.

What benefits of Finlee have been shown in studies?

Low-grade glioma

In an ongoing study, 110 children with low-grade glioma with the BRAF V600E mutation received either Finlee combined with trametinib or chemotherapy with carboplatin and vincristine (other cancer medicines). The main measure of effectiveness was the proportion of children who responded completely or partially to treatment (whose tumour disappeared or shrank) after at least 32 weeks of treatment. Response to treatment was assessed using body scans and patients' clinical data. Treatment with Finlee and trametinib led to a response in 47% (34 out of 73) of children, compared with 11% (4 out of 37) of children receiving carboplatin and vincristine.

High-grade glioma

In the same ongoing study, 41 children with high-grade glioma with the BRAF V600E mutation received Finlee combined with trametinib. Of these children, 56% (23 out of 41) achieved a complete or partial response to treatment which lasted for an average of 22 months. In the treatment of high-grade glioma, Finlee was not compared with any other treatment or placebo (dummy treatment).

What are the risks associated with Finlee?

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

The most common side effects with Finlee (which may affect more than 1 in 5 people) include fever, rash, headache, vomiting, tiredness, dry skin, diarrhoea, bleeding, nausea (feeling sick), dermatitis acneiform (acne-like rash), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), abdominal (belly) pain and cough.

Why is Finlee authorised in the EU?

Children with low-grade glioma or high-grade glioma have limited treatment options. Finlee in combination with trametinib was shown to be effective in shrinking tumours in children whose cancer cells have a BRAF V600E mutation. Although safety data are limited, side effects are generally considered manageable.

The European Medicines Agency therefore decided that Finlee'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 Finlee?

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

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

Other information about Finlee

Finlee received a marketing authorisation valid throughout the EU on 15 November 2023.

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

This overview was last updated in 11-2023.