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Spexotras (*trametinib*)

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

What is Spexotras and what is it used for?

Spexotras 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, dabrafenib. Spexotras is only used in patients whose glioma cancer cells have a specific mutation (change) in the BRAF gene called BRAF V600E.

Spexotras can be used in children with:

- low-grade glioma who require systemic therapy (a treatment that affects the whole body);
- high-grade glioma when the patient has previously received at least one treatment with radiation or chemotherapy.

Spexotras contains the active substance trametinib.

How is Spexotras used?

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

Spexotras is available as a powder that is dispersed (mixed) into a liquid by the pharmacist. It is then taken daily by mouth. Spexotras is used together with dabrafenib (Finlee) which is taken twice a day. Treatment should continue as long as the patient benefits from it. In case of certain side effects, the doctor may reduce or stop the treatment.

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

How does Spexotras work?

Glioma cells with the BRAF mutation produce an abnormal form of a protein called BRAF. The most commonly observed BRAF mutation is V600E. The abnormal BRAF protein activates other proteins called MEK1 and MEK2 which are involved in stimulating cell division. This results in uncontrolled division of cells and thus development of cancer. The active substance in Spexotras, trametinib, works

by blocking the activity of the MEK proteins, thereby slowing down the growth and spread of the cancer.

What benefits of Spexotras 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 Spexotras combined with dabrafenib 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 Spexotras and dabrafenib 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 Spexotras combined with dabrafenib. 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, Spexotras was not compared with any other treatment or placebo (a dummy treatment).

What are the risks associated with Spexotras?

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

The most common side effects with Spexotras (which may affect more than 1 in 5 people) include fever, rash, headache, vomiting, tiredness, dry skin, diarrhoea, haemorrhage (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 Spexotras authorised in the EU?

Children with low-grade glioma or high-grade glioma have limited treatment options. Spexotras combined with dabrafenib 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 Spexotras' 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 Spexotras?

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

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

Other information about Spexotras

Spexotras received a marketing authorisation valid throughout the EU on 5 January 2024.

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

This overview was last updated in 01-2024.