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Vitrakvi (*larotrectinib*)

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

What is Vitrakvi and what is it used for?

Vitrakvi is a cancer medicine for treating solid tumours with NTRK gene fusion. NTRK gene fusion is a rare genetic abnormality that can occur in tumours from different parts of the body such as the lungs, thyroid glands and intestines.

Vitrakvi is used in patients whose tumours are advanced, have spread to other parts of the body or are not amenable to surgery, and who have no satisfactory alternative treatments.

It contains the active substance larotrectinib.

How is Vitrakvi used?

Vitrakvi is available as a liquid (20 mg per ml) and capsules (25 and 100 mg) and is taken by mouth. Adult patients should take 100 mg twice a day for as long as the cancer is stable and the side effects are acceptable. The dose for children is based on their body surface area (weight and height).

Vitrakvi should be started by a doctor experienced in using cancer medicines and can only be obtained with a prescription. For more information about using Vitrakvi, see the package leaflet or contact your doctor or pharmacist.

How does Vitrakvi work?

Tumours with NTRK gene fusion produce an abnormal protein (TRK fusion protein), which causes the uncontrolled growth of cancer cells. The active substance in Vitrakvi, larotrectinib, blocks the action of this protein, preventing the excessive growth of cancer cells and thereby slowing down the worsening of the cancer.

What benefits of Vitrakvi have been shown in studies?

Three ongoing studies in 102 patients with solid tumours with NTRK gene fusion showed that Vitrakvi is effective at reducing the size of patients' tumours. In these studies, 67% of patients who took Vitrakvi had a reduction in the size of their tumours, and the tumours on average shrank to less than half their original size. In addition, the tumours shrank quickly (within 2 months).

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

What are the risks associated with Vitrakvi?

The most common side effects with Vitrakvi (which may affect more than 1 in 5 people) are tiredness, dizziness, constipation, nausea, vomiting, anaemia (low red blood cell counts) and high blood levels of alanine aminotransferase and aspartate aminotransferase (a sign of liver problems).

Most side effects are mild to moderate. For the full list of side effects and restrictions, see the package leaflet.

Why is Vitrakvi authorised in the EU?

Vitrakvi differs from many other cancer medicines by targeting certain tumours with a specific gene arrangement wherever they occur in the body. Although studies are still underway, the results released so far show that it is effective at reducing the size of patients' tumours. In addition, the short time taken to shrink the tumours is important in relieving patients' symptoms.

As for its safety, the side effects of Vitrakvi appear manageable. The European Medicines Agency therefore concluded that its benefits are greater than its risks and that it can be authorised for use in the EU.

Vitrakvi has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Vitrakvi?

Since Vitrakvi has been given conditional authorisation, the company that markets Vitrakvi will provide further data on its effects. This data will come from the three ongoing studies which aim to confirm the benefits and safety of Vitrakvi and its longer term effect in children.

What measures are being taken to ensure the safe and effective use of Vitrakvi?

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

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

Other information about Vitrakvi

Vitrakvi received a conditional marketing authorisation valid throughout the EU on 19 September 2019. Further information on Vitrakvi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vitrakvi.

This overview was last updated in 10-2019.