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Fruzaqla (*fruquintinib*)

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

What is Fruzaqla and what is it used for?

Fruzaqla is a cancer medicine used to treat adults with metastatic colorectal cancer (cancer of the large intestine and rectum that has spread to other parts of the body). It is used in people who have already received standard treatment and whose disease has got worse with treatment with trifluridine-tipiracil or regorafenib (other medicines to treat colorectal cancer) or who could not tolerate either of these medicines.

Fruzaqla contains the active substance fruquintinib.

How is Fruzaqla used?

Fruzaqla can only be obtained with a prescription and treatment should be started by a doctor experienced in giving cancer medicines.

The medicine is available as capsules to be taken by mouth. It is taken once a day for 21 days, followed by a 7-day rest period during which no medicine is taken. This 28-day treatment cycle should continue until the cancer gets worse. If the patient develops unacceptable side effects, the doctor may lower the dose or interrupt or stop treatment.

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

How does Fruzaqla work?

The active substance in Fruzaqla, fruquintinib, works by blocking the activity of proteins known as vascular endothelial growth factor (VEGF) receptors, which are found on the surface of cancer cells. These receptors are involved in the growth and spread of cancer cells and the development of blood vessels that supply the tumour. By blocking VEGF receptors, Fruzaqla helps to reduce the growth and spread of the cancer and cut off the blood supply that keeps cancer cells growing.

What benefits of Fruzaqla have been shown in studies?

A main study involved 691 adults with metastatic colorectal cancer whose cancer was no longer responding to treatment with trifluridine-tipiracil or regorafenib or who could not tolerate either of

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these medicines. The results of the study showed that Fruzaqla was more effective than placebo (a dummy treatment) at increasing the time people lived. In this study, people treated with Fruzaqla lived for an average of 7.4 months compared with 4.8 months for those who received placebo.

The study also showed that people treated with Fruzaqla lived for an average of 3.7 months without their disease getting worse, compared with an average of 1.8 months for people who received placebo.

What are the risks associated with Fruzaqla?

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

The most common side effects with Fruzaqla (which may affect more than 1 in 10 people) include hypertension (high blood pressure), loss of appetite (anorexia), proteinuria (excess protein in the urine), palmar-plantar erythrodysaesthesia syndrome (rash and numbness on the palms and soles), hypothyroidism (underactive thyroid gland), dysphonia (changes in the sound or tone of the voice), diarrhoea and weakness.

The most common serious side effects with Fruzaqla (which may affect up to 1 in 20 people) include gastrointestinal haemorrhage (bleeding in the stomach or intestines), pneumonia (lung infection), hypertension and gastrointestinal perforation (a hole in the wall of the stomach or intestines).

Why is Fruzaqla authorised in the EU?

At the time of approval, there were very limited treatment options for people with metastatic colorectal cancer who no longer respond to treatment. The study showed that Fruzaqla increases the time these people live. The side effects with Fruzaqla are similar to those of other medicines that work in the same way and are considered acceptable.

The European Medicines Agency therefore decided that Fruzaqla'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 Fruzaqla?

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

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

Other information about Fruzaqla

Fruzaqla received a marketing authorisation valid throughout the EU on 20 June 2024.

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

This overview was last updated in 06-2024.