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Qinlock (*ripretinib*)

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

What is Qinlock and what is it used for?

Qinlock is a cancer medicine used to treat gastrointestinal stromal tumour (GIST), a cancer of the stomach and bowel, in adults with advanced disease who have already been treated with three or more medicines of the 'kinase inhibitor' class, including a medicine called imatinib.

GIST is rare, and Qinlock was designated an 'orphan medicine' (a medicine used in rare diseases) on 12 October 2017. Further information on the orphan designation can be found here: www.ema.europa.eu/medicines/human/orphan-designations/eu3171936.

Qinlock contains the active substance ripretinib.

How is Qinlock used?

Qinlock is available as tablets to be taken by mouth and can only be obtained with a prescription. Treatment should be started by a doctor experienced in the treatment of cancer.

The recommended dose is 150 mg per day, taken at the same time each day. Treatment may be paused or the dose reduced to 100 mg per day if side effects are not tolerable. Treatment should continue as long as the patient benefits from it, or the side effects become unmanageable.

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

How does Qinlock work?

The active substance in Qinlock, ripretinib, is one of a group of cancer medicines called receptor tyrosine kinase inhibitors. It works by blocking the activity of receptors (targets) called KIT and PDGFRA on the surface of cancer cells. These receptors help to control cell growth but can be abnormal (mutated) in GIST cancer cells, causing the cells to multiply uncontrollably. By blocking the action of the abnormal receptors, the medicine is expected to help to slow down the tumour growth.

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What benefits of Qinlock have been shown in studies?

Qinlock was shown to be effective at treating GIST in a study involving 129 patients who had been previously treated with, or could not tolerate, at least three other cancer medicines. The study showed that patients treated with Qinlock lived on average for 27.6 weeks without their disease getting worse, compared with 4.1 weeks for patients given placebo (a dummy treatment).

What are the risks associated with Qinlock?

The most common side effects with Qinlock (which may affect more than 1 in 4 people) are tiredness, hair loss, nausea (feeling sick), muscle pain, constipation, diarrhoea, palmar-plantar erythrodysaesthesia syndrome (PPES, rash and numbness on the palms and soles), weight loss and vomiting.

For the full list of side effects and restriction of Qinlock, see the package leaflet.

Why is Qinlock authorised in the EU?

Qinlock was shown to be effective at slowing down the progress of the disease in patients with GIST who had been treated with at least three other medicines. Qinlock was shown to have a favourable safety profile with manageable side effects.

The European Medicines Agency therefore decided that Qinlock'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 Qinlock?

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

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

Other information about Qinlock

Qinlock received a marketing authorisation valid throughout the EU on 18 November 2021.

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

This overview was last updated in 11-2021.