



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 April 2024  
EMA/CHMP/168563/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Fruzaqla fruquintinib

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fruzaqla, intended for the treatment of patients with previously treated metastatic colorectal cancer (mCRC).

The applicant for this medicinal product is Takeda Pharmaceuticals International AG Ireland Branch.

Fruzaqla will be available as 1 and 5 mg hard capsules. The active substance of Fruzaqla is fruquintinib, an antineoplastic agent and vascular endothelial growth factor receptor (VEGFR)-tyrosine kinase inhibitor (ATC code: L01EK04). Fruzaqla is a selective inhibitor of the tyrosine kinases VEGFR-1, 2 and 3, which antitumor effects result from the suppression of tumour angiogenesis.

The benefits of Fruzaqla are a reduction in the risk of death and an increased overall survival (OS) in patients with previously treated metastatic colorectal cancer, compared to placebo. The most common side effects with Fruzaqla are hypertension, anorexia, proteinuria, PPES, hypothyroidism, dysphonia, diarrhoea, and asthenia.

The full indication is:

FRUZAQLA as monotherapy is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib.

Fruzaqla treatment should be initiated by a physician experienced in the administration of anticancer therapy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.