

**FRUZAQLA
(fruquintinib)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Fruzaqla (fruquintinib) is a small molecule kinase inhibitor of vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3. In vitro studies showed Fruzaqla inhibited VEGF-mediated endothelial cell proliferation and tubular formation. In vitro and in vivo studies showed Fruzaqla inhibited VEGF-induced and VEGFR-2 phosphorylation. In vivo studies showed Fruzaqla inhibited tumor growth in a tumor xenograft mouse model of colon cancer (1).

Regulatory Status

FDA-approved indication: Fruzaqla is a kinase inhibitor indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy (1).

Fruzaqla use can increase the risk for hypertension, hemorrhagic events, infections, gastrointestinal perforation, hepatotoxicity, proteinuria, palmar-plantar erythrodysesthesia, posterior reversible encephalopathy syndrome (PRES), impaired wound healing, and arterial thromboembolic events. Fruzaqla contains FD&C yellow No.5 (tartrazine) and No. 6 (sunset yellow FCF) as color additives, which may cause allergic reactions in certain susceptible patients (1).

Fruzaqla may cause fetal harm when administered to pregnant women. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Fruzaqla and for 2 weeks after the last dose (1).

The safety and efficacy of Fruzaqla in pediatric patients have not been established (1).

Summary

Fruzaqla is a kinase inhibitor indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. The safety and efficacy of Fruzaqla in pediatric patients have not been established. Fruzaqla may increase the risk of hypertension, hemorrhagic events,

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infections, gastrointestinal perforation, hepatotoxicity, proteinuria, palmar-plantar erythrodysesthesia, posterior reversible encephalopathy syndrome (PRES), impaired wound healing, and arterial thromboembolic events (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Fruzaqla while maintaining optimal therapeutic outcomes.

References

1. Fruzaqla [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2023.
2. NCCN Drugs & Biologics Compendium® Fruquintinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 28, 2025.