Fruzaqla™

(fruquintinib) capsules

5 mg • 1 mg

Access Guide

INDICATION

FRUZAQLA is 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.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Please see page 3 for information about Takeda Oncology Here2Assist®.

Takeda | ONCOLOGY

Distribution Details for FRUZAQLA™ (fruquintinib)[1]

Product name	FRUZAQLA™ (fruquintinib) capsules, for oral use
Distributed and marketed by	Takeda Pharmaceuticals America, Inc.
Storage and handling	Store at 20 °C to 25 °C (68 °F to 77 °F). Brief exposure to 15 °C and 30 °C (59 °F to 86 °F) permitted (see USP Controlled Room Temperature). Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Recommended dosing	The recommended dosage of FRUZAQLA is 5 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

How supplied

Strength	Count	NDC
1 mg	Bottle of 21 capsules	63020-210-21
5 mg	Bottle of 21 capsules	63020-225-21

Capsules:

- 1 mg: Size 3 hard gelatin capsule with yellow opaque cap and white opaque body, imprinted with "HM013" over "1 mg" on the body in black ink
- 5 mg: Size 1 hard gelatin capsule with a red opaque cap and white opaque body, imprinted with "HM013" over "5 mg" on the body in black ink

Specialty Distributor
(Qualified entities* only)

FRUZAQLA may be purchased directly from the following distribution partners:

ASD Healthcare	Cardinal Health Specialty Distribution	McKesson Plasma & Biologics	McKesson Specialty Care Distribution	Oncology Supply
1-844-222-2273	1-855-855-0708	1-877-625-2566	1-800-482-6700	1-800-633-7555

Ordering

FRUZAQLA can be ordered from one of the following Specialty Pharmacies:

Biologics
1-800-850-4306

Onco360
1-877-662-6633

FRUZAQLA must be filled through one of these in-network specialty pharmacies. Sending a FRUZAQLA prescription to an alternate pharmacy may result in delay or nonfulfillment of the prescription.

NDC, National Drug Code; USP, United States Pharmacopeia.

*Qualified entities for direct purchase include hospitals, physician practices, and institutions that have been licensed by a state agency to dispense pharmaceutical products to appropriate patients. Direct purchase is not available to specialty pharmacy providers or retail pharmacies who are not themselves part of a qualified entity. Eligible government entities include the Department of Defense (DoD), Department of Veterans Affairs, and 340B covered entities.

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Takeda Oncology Here2Assist®

We're here to help your patients with their coverage, financial, and educational resource needs

Takeda Oncology Here2Assist®

- Works with your patients' insurance company to help get your patient started on their medication
- Identifies available financial assistance that may be right for your patients
- May help eligible patients get started on treatment in the event of an insurance delay
- Identifies specialty pharmacies to help fill and ship your patients' prescriptions appropriately
- Conducts regular follow-up calls to patients
- Sends text message status updates and reminders to patients*
- Connects your patients with nurse navigators to support their product education journey†

For more information about patient access support and financial assistance that your patients may qualify for, call us at 1-844-817-6468, Option 2. Let's Talk. We're available Monday-Friday, 8AM–8PM ET, or visit us at www.Here2Assist.com/hcp to learn more.

The Takeda Oncology Here2Assist RapidStart Program

If your patient experiences a delay in insurance coverage determination of at least 5 business days, your patient may be eligible to receive a 1-month supply of medication at no cost to them. Terms and Conditions apply.‡

Visit www.Here2Assist.com to download the appropriate RapidStart Request Form.

Takeda Oncology Co-Pay Assistance Program

For patients who are commercially insured and concerned about their out-of-pocket costs, the Takeda Oncology Co-Pay Assistance Program§ may be able to help.

- Your patient could pay as little as $0 per prescription. Terms and Conditions apply§

Your patients will need to enroll in Takeda Oncology Here2Assist to understand whether the Takeda Oncology Co-Pay Assistance Program is right for them. Help eligible patients enroll today.

- **Enroll:** Fill out a Takeda Oncology Here2Assist enrollment from with your patient
- **Call:** Have your patient call a case manager at 1-844-817-6468, Option 2, Monday–Friday, 8AM–8PM ET

Alternatively, your patient can now initiate enrollment digitally at www.Here2Assist.com. If your patient has submitted a digital enrollment, you will be notified and asked to complete the form via fax or email. **Visit www.Here2Assist.com to learn more.**

Takeda Oncology Patient Assistance Program

If your patient is uninsured or the prescribed medication is not covered, the patient may be eligible to receive their Takeda Oncology medication at no cost through our Patient Assistance Program.‖

Visit www.Here2Assist.com to download the Patient Assistance Program Application.

*Patients will need to enroll in the texting program to receive text messages.

†For FRUZAQLA™ (fruquintinib) and ICLUSIG® (ponatinib) patients only.

‡The RapidStart Program provides a 1-month supply of treatment of the prescribed Takeda Oncology medication at no charge for eligible patients new to therapy experiencing a delay in insurance coverage determination of at least 5 business days. There is no purchase obligation by virtue of a patient's participation in the RapidStart Program. Patients must have an on-label, valid prescription for the Takeda Oncology medication and a medical necessity for being prescribed the Takeda Oncology medication. Patients must be enrolled in the Takeda Oncology Here2Assist Program to qualify. Free product for the RapidStart Program will only be available through the RapidStart Program noncommercial specialty pharmacy. A delay in coverage determination of at least 5 days is required for patients to be eligible for the RapidStart Program. The program may not be combined with any other offer and is not available to patients whose insurers have made a final determination to deny the patient coverage for the prescribed Takeda Oncology medication. Takeda reserves the right to change or end the program at any time. Benefits provided under the program are not transferable.

§By enrolling in the Takeda Oncology Co-Pay Assistance Program (the "Program"), you acknowledge that you currently meet the eligibility criteria and will comply with the following terms and conditions:

You must be at least 18 years old, a resident of the United States or a US Territory, and have commercial (private) prescription insurance that does not cover the entire cost of the medication. The Program is not valid for patients who are enrolled in any state or federal government program, including, but not limited to, Medicare, Medicare Advantage, Medigap, Medicaid, DoD, Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Patients who become eligible for or start using government insurance will no longer be eligible for the Program. The Program is not valid if the entire cost of your prescription is reimbursable by a private insurance plan or other private health or pharmacy benefit programs. You are responsible for reporting receipt of Program assistance to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost, as may be required.

You agree that you will not submit the cost of any portion of the product dispensed pursuant to this Program to a federal or state healthcare program (including, but not limited to, Medicare, Medicare Advantage, Medicaid, TRICARE, VA, DOD, etc.), for purposes of counting it toward your out-of-pocket expenses, and to notify Takeda Oncology Here2Assist if you become eligible for a federal or state healthcare program. This Program is not conditioned on any past, present or future purchase of any Takeda product, including refills. This Program is valid for 12 months, and your co-pay card may be renewed every 12 months, subject to continued eligibility. This offer is not valid with any other program, discount, or offer involving your prescribed Takeda Oncology medication. This offer may be rescinded, revoked, or amended without notice. No reproductions. This offer is void where prohibited by law, taxed, or restricted. Limit one offer per purchase. No income requirements or membership fees. This Program is not health insurance. Cash value of 1/100 of 1¢. For questions about this offer, please contact the Takeda Oncology Co-Pay Assistance Program, a patient support service of Takeda Oncology Here2Assist, at 1-844-817-6468, Option 2, Monday-Friday, 8AM-8PM ET.

‖To be eligible for the Patient Assistance Program, patients must meet certain financial and insurance coverage criteria. A Patient Assistance Program Application must be submitted in order to confirm patient eligibility.

INDICATION

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Hypertension** occurred in 49% of 911 patients with mCRC treated with FRUZAQLA, including Grade 3-4 events in 19%, and hypertensive crisis in three patients (0.3%). Do not initiate FRUZAQLA unless blood pressure is adequately controlled. Monitor blood pressure weekly for the first month and at least monthly thereafter as clinically indicated. Initiate or adjust anti-hypertensive therapy as appropriate. Withhold, reduce dose, or permanently discontinue FRUZAQLA based on severity of hypertension.
- **Hemorrhagic Events** including serious, fatal events can occur with FRUZAQLA. In 911 patients with mCRC treated with FRUZAQLA, 6% of patients experienced gastrointestinal hemorrhage, including 1% with a Grade ≥3 event and 2 patients with fatal hemorrhages. Permanently discontinue FRUZAQLA in patients with severe or life-threatening hemorrhage. Monitor the International Normalized Ratio (INR) levels in patients receiving anticoagulants.
- **Infections.** FRUZAQLA can increase the risk of infections, including fatal infections. In 911 patients with mCRC treated with FRUZAQLA, the most common infections were urinary tract infections (6.8%), upper respiratory tract infections (3.2%) and pneumonia (2.5%); fatal infections included pneumonia (0.4%), sepsis (0.2%), bacterial infection (0.1%), lower respiratory tract infection (0.1%), and septic shock (0.1%). Withhold FRUZAQLA for Grade 3 or 4 infections, or worsening infection of any grade. Resume FRUZAQLA at the same dose when the infection has resolved.
- **Gastrointestinal Perforation** occurred in patients treated with FRUZAQLA. In 911 patients with mCRC treated with FRUZAQLA, 1.3% experienced a Grade ≥3 gastrointestinal perforation, including one fatal event. Permanently discontinue FRUZAQLA in patients who develop gastrointestinal perforation or fistula.
- **Hepatotoxicity.** FRUZAQLA can cause liver injury. In 911 patients with mCRC treated with FRUZAQLA, 48% experienced increased ALT or AST, including Grade ≥3 events in 5%, and fatal events in 0.2% of patients. Monitor liver function tests (ALT, AST, and bilirubin) before initiation and periodically throughout treatment with FRUZAQLA. Temporarily hold and then reduce or permanently discontinue FRUZAQLA depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests.
- **Proteinuria.** FRUZAQLA can cause proteinuria. In 911 patients with mCRC treated with FRUZAQLA, 36% experienced proteinuria and 2.5% of patients experienced Grade ≥3 events. Monitor for proteinuria before initiation and periodically throughout treatment with FRUZAQLA. For proteinuria ≥2g/24 hours, withhold FRUZAQLA until improvement to ≤Grade 1 proteinuria and resume FRUZAQLA at a reduced dose. Discontinue FRUZAQLA in patients who develop nephrotic syndrome.
- **Palmar-Plantar Erythrodysesthesia (PPE)** occurred in 35% of 911 patients treated with FRUZAQLA, including 8% with Grade 3 events. Based on severity of PPE, withhold FRUZAQLA and then resume at the same or reduced dose.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- **Posterior Reversible Encephalopathy Syndrome (PRES)**, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in one of 911 patients treated with FRUZAQLA. Perform an evaluation for PRES in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue FRUZAQLA in patients who develop PRES.
- **Impaired Wound Healing.** In 911 patients with mCRC treated with FRUZAQLA, 1 patient experienced a Grade 2 event of wound dehiscence. Do not administer FRUZAQLA for at least 2 weeks prior to major surgery. Do not administer FRUZAQLA for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of FRUZAQLA after resolution of wound healing complications has not been established.
- **Arterial Thromboembolic Events.** In 911 patients with mCRC treated with FRUZAQLA, 0.8% of patients experienced an arterial thromboembolic event. Initiation of FRUZAQLA in patients with a recent history of thromboembolic events should be carefully considered. In patients who develop arterial thromboembolism, discontinue FRUZAQLA.
- **Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF).** FRUZAQLA 1 mg capsules contain FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. FRUZAQLA 1 mg contains FD&C Yellow No. 6 (sunset yellow FCF), which may cause allergic reactions.
- **Embryo-Fetal Toxicity.** Based on findings in animal studies and its mechanism of action, FRUZAQLA can cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of childbearing potential and males with female partners of childbearing potential to use effective contraception during treatment with FRUZAQLA and for 2 weeks after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥20%) following treatment with FRUZAQLA included hypertension, palmar-plantar erythrodysesthesia (hand-foot skin reactions), proteinuria, dysphonia, abdominal pain, diarrhea, and asthenia.

DRUG INTERACTIONS: Avoid concomitant administration of FRUZAQLA with strong or moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Advise women not to breastfeed during treatment with FRUZAQLA and for 2 weeks after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-662-8532 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch.**

Please see full Prescribing Information.

To learn more about FRUZAQLA, please visit **fruzaqlahcp.com**.

Reference: 1. FRUZAQLA. Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc.; November 2023.

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