


WHAT TO EXPECT WHEN STARTING FRUZAQLA

An
innovation
in mCRC

You have just been prescribed FRUZAQLA, **a non-chemotherapy pill taken once a day** for previously treated metastatic colorectal cancer (mCRC). In this guide, you will find:

- ✓ Tips for fitting FRUZAQLA into your daily routine
- ✓ The most common side effects with FRUZAQLA
- ✓ A place to write down notes and questions you may have about treatment

A guide for staying on track with treatment

 **Fruzaqla**[®]
(fruquintinib) capsules
5 mg • 1 mg

What is FRUZAQLA[®] (fruquintinib)?

FRUZAQLA is a prescription medicine used to treat adults with colon or rectal cancer that has spread to other parts of the body (metastatic colorectal cancer [mCRC]) and who have received previous treatment with certain anti-cancer medicines.

It is not known if FRUZAQLA is safe and effective in children.

Please see additional Important Safety Information throughout, full Important Safety Information on pages 8-11, and Patient Information in the [Full Prescribing Information](#).

TIPS FOR STAYING ON TRACK WITH TREATMENT



Taking your medication at the same time every day can help you get the most out of treatment.

Use the FRUZAQLA Dosing Calendar to check off each time you take a dose.

Set daily reminders on your phone or download a medication tracking app.


Consider using a weekly pill container to track how many pills you've taken each week.

IMPORTANT SAFETY INFORMATION

FRUZAQLA may cause serious side effects, including:

- **High blood pressure (hypertension).** High blood pressure is common with FRUZAQLA and can also be severe. Your healthcare provider will check your blood pressure before starting treatment with FRUZAQLA, 1 time every week for the first month of treatment, and then at least 1 time a month or more often if needed during treatment. Your healthcare provider may prescribe medicine to treat your high blood pressure if needed. Tell your healthcare provider if you get any of the following symptoms of hypertension during treatment: severe headache, lightheadedness or dizziness, confusion, changes in vision, chest pain, trouble breathing, nosebleeds, or vomiting.

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FRUZAQLA IS A CONVENIENT, NON-CHEMO PILL

FRUZAQLA is a once-daily pill. You will not need to visit an infusion center for treatment.



Take FRUZAQLA once a day.

Most people take 5 mg of FRUZAQLA once daily for the first 21 days, followed by 7 days off treatment for each 28-day cycle.

Your healthcare provider may change your dose of FRUZAQLA if needed.



Take FRUZAQLA with or without food.

Make sure to swallow the pill whole each time.



Take FRUZAQLA at the same time every day.

If you miss a dose of FRUZAQLA, you can take the missed dose within 12 hours on the same day. If more than 12 hours have passed, take your regularly scheduled dose the next day at the usual time.

Do not take 2 doses on the same day to make up for a missed dose.

IMPORTANT SAFETY INFORMATION (continued)

• **Severe bleeding (hemorrhage).** FRUZAQLA can cause bleeding that can be serious and may lead to death. Tell your healthcare provider if you get any of the following symptoms of bleeding during treatment:

- unusual, severe, or bleeding that will not stop
- bruising
- lightheadedness
- vomiting blood or your vomit looks like coffee grinds
- blood in the stool or black stool that looks like tar
- blood in the urine or urine that looks red, pink, or brown
- coughing up blood or blood clots
- menstrual bleeding that is heavier than normal
- unusual vaginal bleeding
- nose bleeds that happen often

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SIDE EFFECTS WERE GENERALLY MANAGEABLE IN FRESCO-2

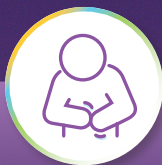
FRESCO-2 was a study that examined how well FRUZAQLA worked and how safe it was to take.* It found that most side effects with FRUZAQLA were manageable, and that most people were able to stay on treatment. “Manageable” means that the side effects are able to be managed by pausing or reducing the dose of FRUZAQLA or stopping treatment.

- 1 out of 5 people (20%) needed to stop taking FRUZAQLA because of side effects
- Less than half of people (47%) needed to pause their dose
- 1 out of 4 people (24%) needed to reduce their dose

The most common side effects included:



Voice changes or hoarseness



Stomach-area (abdominal) pain



Diarrhea



Weakness, lack of strength and energy, and feeling very tired or sleepy (asthenia)


- These are not all the possible side effects of FRUZAQLA
- 38% of people treated with FRUZAQLA had serious side effects
- The **most common serious side effects** were severe bleeding (hemorrhage) and a tear in the stomach or intestinal wall (gastrointestinal perforation)

*FRESCO-2 included 691 adults with CRC. It compared people taking FRUZAQLA plus best supportive care with people taking a placebo (sugar pill) plus best supportive care.

IMPORTANT SAFETY INFORMATION (continued)

- **Infections.** FRUZAQLA can increase the risk of infections, including serious infections that can lead to death. The most common infections with FRUZAQLA happened in the urinary tract, nose or throat, and lungs. Tell your healthcare provider if you get any of the following symptoms of infection during treatment: fever, severe cough with or without an increase in mucus (sputum) production, severe sore throat, trouble breathing, burning or pain when you urinate, or redness, swelling, or pain in any part of the body.

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Be sure to tell your care team about any side effects you have.

They may be able to help you find ways to manage them. Your doctor may change your dose of FRUZAQLA.

Your doctor may also pause or stop treatment with FRUZAQLA.



In FRESCO-2, 80% of people were able to stay on FRUZAQLA




IMPORTANT SAFETY INFORMATION (continued)

• **A tear in your stomach or intestinal wall (gastrointestinal perforation).**

FRUZAQLA can cause gastrointestinal perforation that can be serious and may lead to death. Tell your healthcare provider right away if you get any of the following symptoms of gastrointestinal perforation during treatment: severe stomach (abdominal) pain or stomach pain that does not go away, vomiting or vomiting blood, blood in the stool or black stool that looks like tar, fever or chills, or nausea.

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WAYS TO TAKE AN ACTIVE ROLE IN YOUR TREATMENT

Write down all instructions from your healthcare team.

Create a routine that fits treatment into your everyday life.


Keep a list of questions or observations that you have while taking FRUZAQLA.



IMPORTANT SAFETY INFORMATION (continued)

- **Liver problems.** Increased liver enzymes in your blood are common with FRUZAQLA and can also be severe and may lead to death. Your healthcare provider will do blood tests before and during treatment with FRUZAQLA to check for liver problems. Tell your healthcare provider if you get any of the following symptoms of liver problems during treatment: yellowing of your skin or the white part of your eyes, dark-colored (tea-colored) urine, pain in your right upper stomach area (abdomen), loss of appetite, nausea or vomiting, or bleeding or bruising.

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Use this page to write down any tips, notes, or instructions from your doctor or pharmacist.



Take FRUZAQLA exactly as your doctor tells you

If you have any questions about FRUZAQLA or your dosing, talk to your doctor or pharmacist as soon as possible.

IMPORTANT SAFETY INFORMATION (continued)

- **Protein in your urine (proteinuria).** Protein in your urine is common with FRUZAQLA and can also be severe. Your healthcare provider will check your urine for protein before starting and during treatment with FRUZAQLA. Tell your healthcare provider if you have to urinate more than usual or if you get swelling of your face, hands, arms, legs, or feet during treatment.

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IMPORTANT SAFETY INFORMATION

What is FRUZAQLA® (fruquintinib)?

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It is not known if FRUZAQLA is safe and effective in children.

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- **High blood pressure (hypertension).** High blood pressure is common with FRUZAQLA and can also be severe. Your healthcare provider will check your blood pressure before starting treatment with FRUZAQLA, 1 time every week for the first month of treatment, and then at least 1 time a month or more often if needed during treatment. Your healthcare provider may prescribe medicine to treat your high blood pressure if needed. Tell your healthcare provider if you get any of the following symptoms of hypertension during treatment: severe headache, lightheadedness or dizziness, confusion, changes in vision, chest pain, trouble breathing, nosebleeds, or vomiting.
- **Severe bleeding (hemorrhage).** FRUZAQLA can cause bleeding that can be serious and may lead to death. Tell your healthcare provider if you get any of the following symptoms of bleeding during treatment:
 - unusual, severe, or bleeding that will not stop
 - bruising
 - lightheadedness
 - vomiting blood or your vomit looks like coffee grinds
 - blood in the stool or black stool that looks like tar
 - blood in the urine or urine that looks red, pink, or brown
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- **A tear in your stomach or intestinal wall (gastrointestinal perforation).** FRUZAQLA can cause gastrointestinal perforation that can be serious and may lead to death. Tell your healthcare provider right away if you get any of the following symptoms of gastrointestinal perforation during treatment: severe stomach (abdominal) pain or stomach pain that does not go away, vomiting or vomiting blood, blood in the stool or black stool that looks like tar, fever or chills, or nausea.
- **Liver problems.** Increased liver enzymes in your blood are common with FRUZAQLA and can also be severe and may lead to death. Your healthcare provider will do blood tests before and during treatment with FRUZAQLA to check for liver problems. Tell your healthcare provider if you get any of the following symptoms of liver problems during treatment: yellowing of your skin or the white part of your eyes, dark-colored (tea-colored) urine, pain in your right upper stomach area (abdomen), loss of appetite, nausea or vomiting, or bleeding or bruising.
- **Protein in your urine (proteinuria).** Protein in your urine is common with FRUZAQLA and can also be severe. Your healthcare provider will check your urine for protein before starting and during treatment with FRUZAQLA. Tell your healthcare provider if you have to urinate more than usual or if you get swelling of your face, hands, arms, legs, or feet during treatment.
- **Hand-foot skin reactions (Palmar-Plantar Erythrodysesthesia [PPE]).** Hand-foot skin reactions are common with FRUZAQLA and can also be severe. Tell your healthcare provider if you get a severe rash or redness, pain, blisters, bleeding, or swelling on the palms of your hands or soles of your feet during treatment.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** PRES is a serious condition that can happen in your brain during treatment with FRUZAQLA. Tell your healthcare provider right away if you get any of the following symptoms during treatment: headache, seizures, confusion, changes in vision, or problems thinking.
- **Wound healing problems.** Wounds may not heal properly during treatment with FRUZAQLA. Tell your healthcare provider if you plan to have any surgery before starting FRUZAQLA or during treatment. You should stop taking FRUZAQLA at least 2 weeks before planned surgery. Your healthcare provider will tell you when you may start taking FRUZAQLA again after surgery.

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IMPORTANT SAFETY INFORMATION (continued)

- **Blood clots in your blood vessels (arteries).** FRUZAQLA can cause blood clots or blockage in your blood vessels that may lead to heart attack, stroke, or death. Get medical help right away if you get any of the following symptoms during treatment:
 - severe chest pain or pressure
 - pain in your arms, legs, back, neck or jaw
 - shortness of breath
 - numbness or weakness of your face, arm, or leg, especially on one side of your body
 - feeling lightheaded or faint
 - sweating more than usual
 - sudden confusion, trouble talking or understanding things
 - trouble walking
 - sudden severe headache
 - sudden vision changes in one or both eyes
 - dizziness or loss of balance or coordination
- **Allergic reactions to FD&C Yellow No. 5 and FD&C Yellow No. 6.** FRUZAQLA 1mg capsules contain the inactive ingredients FD&C Yellow No. 5 (tartrazine) and FD&C Yellow No. 6 (sunset yellow FCF). FD&C Yellow No. 5 (tartrazine) can cause allergic-type reactions (including bronchial asthma) in certain people, especially people who also have an allergy to aspirin. FD&C Yellow No. 6 (sunset yellow FCF) can also cause allergic reactions. Tell your healthcare provider if you get hives, rash, or trouble breathing during treatment with FRUZAQLA.

The most common side effects of FRUZAQLA include:


- voice changes or hoarseness
- stomach-area (abdominal) pain
- diarrhea
- weakness, lack of strength and energy, and feeling very tired or sleepy (asthenia)

These are not all of the possible side effects of FRUZAQLA. Call your doctor for medical advice about side effects. **You may report side effects to Takeda at 1-844-662-8532 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before taking FRUZAQLA, tell your healthcare provider about all your medical conditions, including if you:

- Have high blood pressure.
- Have bleeding problems
- Have an infection
- Have liver or kidney problems

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IMPORTANT SAFETY INFORMATION (continued)

- Plan to have surgery or have had recent surgery. You should stop taking FRUZAQLA at least 2 weeks before your planned surgery. Your healthcare provider will tell you when you can start FRUZAQLA again after your surgery
- Have recently had a blood clot, stroke, or heart attack
- Are allergic to FD&C Yellow No. 5 (tartrazine) or FD&C Yellow No. 6 (sunset yellow FCF)
- Are pregnant or plan to become pregnant. FRUZAQLA can harm your unborn baby. You should not become pregnant during treatment with FRUZAQLA.

Females who can become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with FRUZAQLA.
- Use effective birth control (contraception) during treatment and for 2 weeks after your last dose of FRUZAQLA.
- Tell your healthcare provider right away if you become pregnant during treatment with FRUZAQLA.

Males with female partners who can become pregnant:


- Use effective birth control during treatment and for 2 weeks after your last dose of FRUZAQLA.
- Tell your healthcare provider right away if your partner becomes pregnant during your treatment with FRUZAQLA.
- Are breastfeeding or plan to breastfeed. It is not known if FRUZAQLA passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of FRUZAQLA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FRUZAQLA may affect the way other medicines work, and other medicines may affect how FRUZAQLA works.

Especially tell your healthcare provider if you take blood thinners (anticoagulants).

Know the medicines you take. Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.


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YOUR TREATMENT WITH FRUZAQLA BEGINS HERE



Continue working with your doctor as you take the next steps in your treatment journey

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ONCOLOGY

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