

PATIENT INFORMATION

FRUZAQLA® (fru-zahk-la)
(fruquintinib)
capsules

What is FRUZAQLA?

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.

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

- have high blood pressure.
- have bleeding problems.
- have an infection.
- have liver or kidney problems.
- 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. See **“What are the possible side effects of FRUZAQLA?”**
- 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). See **“What are the possible side effects of FRUZAQLA?”**
- 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.

How should I take FRUZAQLA?

- Take FRUZAQLA exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with FRUZAQLA if you have certain side effects. **Do not** change your dose or stop taking FRUZAQLA unless your healthcare provider tells you.
- You will usually take FRUZAQLA 1 time a day for 21 days (3 weeks) and then stop for 7 days (1 week). This is 1 cycle of treatment. Repeat this cycle for as long as your healthcare provider tells you.
- Take FRUZAQLA about the same time each day with or without food and swallow the capsule whole.
- 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 at the same time to make up for the missed dose.
- **Do not** take another dose if you vomit after taking FRUZAQLA. Take your regularly scheduled dose the next day at the usual time.
- If you take too much FRUZAQLA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of FRUZAQLA?

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
- 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
- coughing up blood or blood clots
- menstrual bleeding that is heavier than normal
- unusual vaginal bleeding
- nose bleeds that happen often

- **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
- redness, swelling or pain in any part of the body

- **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
- 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
- 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
- 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.

- **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 1 mg 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
- diarrhea
- stomach-area (abdominal) pain
- weakness, lack of strength and energy, and feeling very tired or sleepy (asthenia)

FRUZAQLA may cause fertility problems in females, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

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 FDA at 1-800-FDA-1088.

How should I store FRUZAQLA?

- Store FRUZAQLA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep FRUZAQLA dry and away from moisture.
- The FRUZAQLA bottle comes with a child resistant closure.
- Safely throw away (discard of) any unused FRUZAQLA.

Keep FRUZAQLA and all medicines out of the reach of children.

General information about the safe and effective use of FRUZAQLA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use FRUZAQLA for a condition for which it was not prescribed. Do not give FRUZAQLA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about FRUZAQLA that is written for health professionals.

What are the ingredients in FRUZAQLA?

Active ingredient: fruquintinib

Inactive ingredients: corn starch, microcrystalline cellulose, talc

Capsule shell:

- 1 mg capsule: FD&C Yellow No. 5 (tartrazine), FD&C Yellow No. 6 (sunset yellow FCF), gelatin, and titanium dioxide
- 5 mg capsule: FD&C Blue No. 1 (brilliant blue FCF), FD&C Red No. 40 (allura red AC), gelatin, and titanium dioxide

Printing ink: butanol, dehydrated alcohol, ferrousferic oxide, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, and strong ammonia solution.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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