

Fruquintinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for colon or rectal (colorectal) cancer (CRC).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Fruquintinib (froo-KWIN-tih-nib): Fruzaqla (froo-ZAH-klah)	Slows down or stops the growth of cancer cells by blocking specific proteins involved in tumor growth and the formation of blood vessels.	Capsule(s) taken by mouth.

Treatment Administration and Schedule

Fruquintinib is typically taken by mouth 1 time a day for 21 days, followed by a 7-day rest period. This 28-day length of time is called a “cycle”.

Your fruquintinib dosing instructions:

- Fruquintinib comes in 2 capsule strengths: 1 mg and 5 mg.
- Your dose might differ, but fruquintinib is typically taken as 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 care team tells you.
- Take fruquintinib about the same time each day with or without food and swallow the capsule whole. Do not chew, crush or open the capsule.
- Do not change your dose or stop taking fruquintinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking fruquintinib if you develop certain side effects.
- If you miss a dose of fruquintinib, 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 fruquintinib. Take your regularly scheduled dose the next day at the usual time.
- If you take too much fruquintinib, call your care team or go to the nearest hospital emergency room right away.

Treatment Administration and Schedule Continued

Treatment Name	Cycle 1, Days																						Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22-28	Day 1
Fruquintinib	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Week-long Break	✓

Storage and Handling of Fruquintinib

- Store fruquintinib at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep fruquintinib dry and away from moisture.
- The fruquintinib bottle comes with a child resistant closure.
- Keep fruquintinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused fruquintinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	
To help prevent hand-foot skin reaction (HFSR)	
Other	

Common Side Effects

Side Effect	Important Information
Low Platelet Count (Thrombocytopenia)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak or very tired, or may make you look pale. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
High Blood Pressure (Hypertension)	Description: High blood pressure means the force of blood against your artery walls is too high. Treatment can raise your blood pressure or make it harder to control. Recommendations: • Exercise regularly, maintain a healthy weight, and limit alcohol and salt (sodium). • Take blood pressure medicines as prescribed. Your care team may change your medicines if needed. • Your care team may ask you to check and record your blood pressure at home. Bring readings to appointments. • Follow diet and lifestyle advice from your care team. Talk to your care team if you have: • Severe or new headaches • Dizziness or lightheadedness • Blurred vision • Trouble breathing • Nosebleeds that do not stop • A pounding sensation in your chest, neck, or ears • Irregular or fast heartbeats • Chest pain or pressure
High Cholesterol and Triglycerides Levels in Your Blood (Hyperlipidemia)	Description: Treatment can raise cholesterol and triglyceride levels in your blood. While cholesterol is needed by the body, high levels can increase the risk of heart disease. Triglycerides are blood fats, and very high levels can increase your risk of pancreatitis and heart problems. Recommendations: • Adopt a diet low in saturated and trans fats, increase fiber intake, and engage in regular physical activity. • Maintain a healthy weight. • Get regular cholesterol tests and inform the care team of any significant changes. • Do not smoke and limit alcohol consumption. Talk to your care team if you have: • Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain

Mouth Sores or Irritation (Mucositis or Stomatitis)	Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling. Recommendations: • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. Talk to your care team if you have: • Painful mouth sores or throat pain • Trouble eating or significant weight loss
Voice Changes or Hoarseness	Description: Hoarseness is when you have a weak, rough, or harsh voice. Recommendations: • Drink plenty of water and avoiding irritants (e.g., dust, smoke, alcohol, industrial chemicals). • Write things down to give your voice a break. • Avoid shouting or whispering. Talk to your care team if you have: • Severe hoarseness • Pain or soreness in the throat
Liver Problems	Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite

High Blood Sugar (Hyperglycemia)	Description: Treatment may cause high blood sugar levels. Your care team may perform blood tests to check for these changes and treat you if needed. Recommendations: • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. Talk to your care team if you have: • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar
Hand-Foot Skin Reaction (HFSR)	Description: HFSR causes dryness, thickening, calluses, blisters, or cracking of the skin on the palms of your hands and soles of your feet. HFSR can lead to a loss of fingerprints, which could impact your identification. Recommendations: • Keep hands and feet moisturized with a non-scented moisturizing cream. • Applying urea 10% or 20% cream twice daily to the affected area may be helpful. • Avoid exposure to hot water on the hands and feet in showers or baths, or when doing dishes, as this may dry out the skin. • Avoid tight-fitting shoes or socks. • Avoid excessive rubbing of hands and feet unless applying lotion. • Wear gloves when working with your hands. Talk to your care team if you have: • Painful blisters or calluses on your hands or feet
Low Sodium Levels in Your Blood (Hyponatremia)	Description: Treatment may cause low levels of sodium in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed. Talk to your care team if you have: • New or worsening confusion, drowsiness, or trouble thinking • Severe headache or nausea/vomiting • Seizures or fainting • Sudden weakness, unsteadiness, or trouble walking • Difficulty breathing

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Severe Bleeding (Hemorrhage)	• Vomiting blood or if your vomit looks like coffee-grounds • Pink or brown urine • Red or black (looks like tar) stools • Coughing up blood or blood clots	• Menstrual bleeding that is heavier than normal • Unusual vaginal bleeding • Nose bleeds that happen often • Bruising • Lightheadedness
Blood Clots or Blockage (Thrombosis) in Your Blood Vessels (Arteries)	• Chest pain or pressure • Swelling or pain in your arms, back, neck, or jaw • Shortness of breath • Numbness or weakness on one side of your body	• Trouble talking • Headache • Vision changes
A Tear in Your Stomach or Intestinal Wall (Perforation) or an Abnormal Connection Between 2 Parts of Your Body (Fistula)	• Severe pain or tenderness in your stomach area (abdomen) • Swelling of the abdomen • Fever of 100.4°F (38°C) or higher • Chills	• Nausea • Vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)
Posterior Reversible Encephalopathy Syndrome (PRES)	A neurologic condition called PRES can happen during treatment with fruquintinib. • Severe headache • Confusion • Weakness • Seizures • Blindness or change in vision	
Infections	• Fever of 100.4°F (38°C) or higher • Severe cough with or without an increase in mucus (sputum) production • Severe sore throat	• Shortness of breath • Burning or pain when urinating • Unusual vaginal discharge or irritation • Redness, swelling, or pain in any part of the body
Allergic Reaction to FD&C Yellow No. 5 and FD&C Yellow No. 6.	Fruquintinib 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. • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives)	

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may harm an unborn baby.
 - If you are able to become pregnant:
 - Your care team will verify your pregnancy status before treatment.
 - Use an effective method of birth control during treatment and for 2 weeks after your last dose of fruquintinib.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 2 weeks after your last dose of fruquintinib.
- Do not breastfeed during treatment and for 2 weeks after your last dose of fruquintinib.

Additional Information

- **Tell your care team about all the medicines you take.**
 This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Wound healing problems.** Wound healing problems have happened in some people who take fruquintinib. Tell your care team if you plan to have any surgery before or during treatment with fruquintinib.
 - You should stop taking fruquintinib at least 2 weeks before planned surgery.
 - Your care team should tell you when you may start taking fruquintinib again after surgery.
- **This Patient Education Sheet may not describe all possible side effects.**
 Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important Notice:

The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated to gather information and develop this patient education guide. This guide is a summary of the medication, based on information provided by the drug manufacturer and other sources.

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PES-377