

In a clinical study, people with mCRC lived a median of 7.4 months with FRUZAQLA + BSC vs 4.8 months with placebo (sugar pill) + BSC


An
innovation
in mCRC

CLAIM MORE OF YOUR LIFE



BSC=best supportive care;
mCRC=metastatic colorectal cancer.

A guide for patients and their care partners

 **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 14-17, and Patient Information in the [Full Prescribing Information](#).

mCRC AND YOUR TREATMENT



Colorectal cancer can spread to other parts of the body.

This is called metastatic colorectal cancer, or mCRC.

If you or your loved one is living with mCRC, you may be wondering what comes next after your current treatment.

This guide can help you **learn more about FRUZAQLA**. It offers information to help you **take an active role in your treatment**.

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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WHAT'S INSIDE



On these pages, you'll find information about:

- FRUZAQLA for mCRC
- Life with FRUZAQLA
- How FRUZAQLA may help
- Taking FRUZAQLA
- Possible side effects
- Patient support

This guide should not take the place of your doctor's advice. Talk with your care team if you have questions about your cancer or your treatment



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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AN INNOVATIVE FDA-APPROVED TARGETED MEDICINE FOR mCRC

FRUZAQLA is a treatment for adults with colorectal cancer that has spread to other parts of the body (mCRC). It is used by people who have received previous treatment with certain anti-cancer medicines.

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

FRUZAQLA is a targeted therapy. FRUZAQLA is not chemotherapy.




For people with mCRC, FRUZAQLA is a convenient oral treatment with proven survival results that can be taken after chemotherapy and other anti-cancer medications

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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FRUZAQLA WAS STUDIED IN MORE THAN 1100 PEOPLE IN 2 TRIALS

The 2 studies were called FRESCO and FRESCO-2. FRESCO was a single-country study, while FRESCO-2 was a global study. Because FRESCO-2 included adults with mCRC from several countries, this guide focuses on those results. It compared people taking FRUZAQLA plus best supportive care* with people taking placebo (sugar pill) plus best supportive care.

People in FRESCO-2 were between 25 and 86 years old. The median age was 64 years. They had all received chemotherapy in the past.

The study measured a few things about FRUZAQLA, including:



Do people live longer with FRUZAQLA compared with placebo?



Does it take longer for people's mCRC to get worse with FRUZAQLA compared with placebo?



Are people taking FRUZAQLA able to preserve their daily function compared with people taking placebo?



How safe is FRUZAQLA?

*What is best supportive care?

Best supportive care (or BSC) focuses on managing symptoms and keeping you feeling as well as possible. It may include things like counseling or pain management.

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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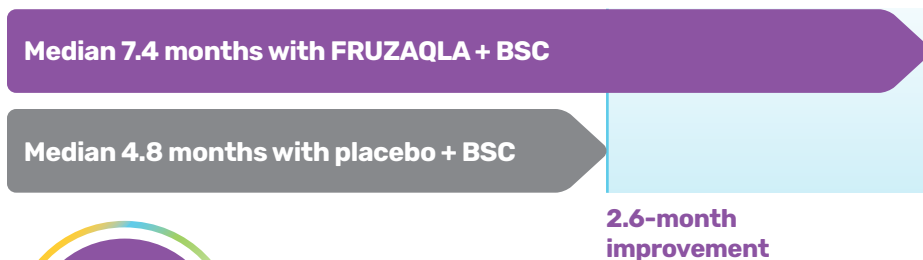
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RESULTS WITH FRUZAQLA

In FRESCO-2, people taking FRUZAQLA lived longer than people taking placebo (sugar pill)



Median is not the same as average

Median is the middle number in a set of measurements arranged from lowest to highest.

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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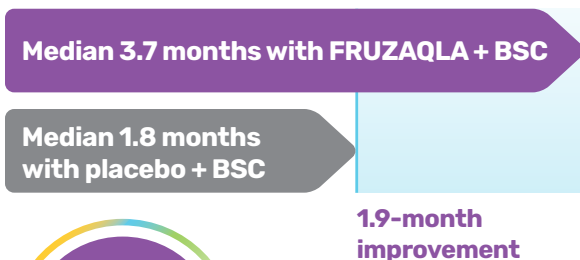


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In FRESCO-2, people taking FRUZAQLA went more than twice as long without their mCRC getting worse compared with those taking placebo (sugar pill)



REDUCED RISK OF mCRC GETTING WORSE



Studied in people like you

Different groups of people were included in the study. These groups differed based on how long people had mCRC, their mutation status, and what anti-cancer medicines they were on before. A consistent benefit was seen with FRUZAQLA across most of these groups.

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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SIDE EFFECTS WERE GENERALLY MANAGEABLE

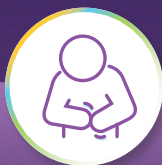
Most side effects with FRUZAQLA were manageable in FRESCO-2, and most people were able to stay on treatment. “Manageable” means that the side effects are able to be managed by pausing or reducing the dose of FRUZAQLA or stopping treatment.

- 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)

IMPORTANT SAFETY INFORMATION (continued)

- **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.

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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)

- **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.

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In the FRESCO-2 study

FRUZAQLA HELPED PRESERVE CERTAIN QUALITY OF LIFE MEASURES

A quality of life survey taken as part of the study showed more than 70% of people taking FRUZAQLA + BSC reported their symptoms staying the same or taking longer to get worse compared with people taking placebo + BSC.

People taking FRUZAQLA completed several questionnaires that used different scales to measure well-being.

- These scales measure **the time it takes for symptoms of cancer to get worse**
- The questions cover how well people lived their lives with the disease (in terms of physical, emotional, and social functioning) and how bad their symptoms were
- The surveys did not consider other factors that can impact how quickly or slowly symptoms of disease progress



What is quality of life?

You might hear your doctor talk about quality of life. This measures a person's physical and emotional well-being. It also measures their **ability to do activities or functions of daily living.**

IMPORTANT SAFETY INFORMATION (continued)

- **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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Symptoms that took longer to get worse with FRUZAQLA + BSC vs placebo + BSC:



Emotional health



Social well-being



Tiredness (fatigue)



Nausea/vomiting



Trouble sleeping (insomnia)

Symptoms that stayed the same with FRUZAQLA + BSC vs placebo + BSC:



Physical health



Brain functions (like memory or attention)



Pain

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

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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.



- 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
- Take FRUZAQLA **with or without food**
- Swallow FRUZAQLA pill whole
- Take each dose at the **same time every day**. If less than 12 hours have passed since you missed a dose of FRUZAQLA, do not take your missed dose. Do not take 2 doses on the same day to make up for a missed dose
- Your doctor may change your dose of FRUZAQLA if needed

Take FRUZAQLA exactly as your doctor tells you

Be sure to talk to your doctor or pharmacist if you have any questions about FRUZAQLA or your dosing.

IMPORTANT SAFETY INFORMATION (continued)

- **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.

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FRUZAQLA treatment doesn't have to get in the way of your daily life.


It can be taken at home or on the go.
It can be taken with or without food.

IMPORTANT SAFETY INFORMATION (continued)

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)

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IMPORTANT SAFETY INFORMATION

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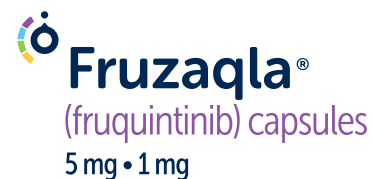
- **High blood pressure (hypertension).** High blood pressure is common with FRUZAQLA and can also be severe. Your healthcare provider will check your blood pressure before starting treatment with FRUZAQLA, 1 time every week for the first month of treatment, and then at least 1 time a month or more often 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
 - coughing up blood or blood clots
 - menstrual bleeding that is heavier than normal
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 - nose bleeds that happen often

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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.
- **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.



Please see Important Safety Information continued on the next page and Patient Information in the [Full Prescribing Information](#).

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.

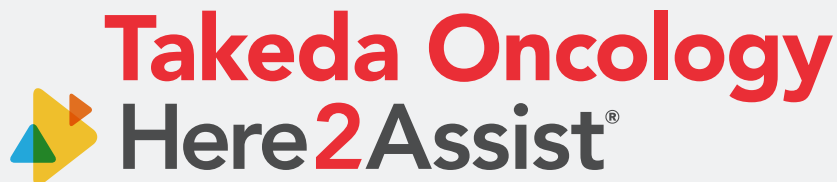
Especially tell your healthcare provider if you take blood thinners (anticoagulants).

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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WE'RE HERE TO HELP



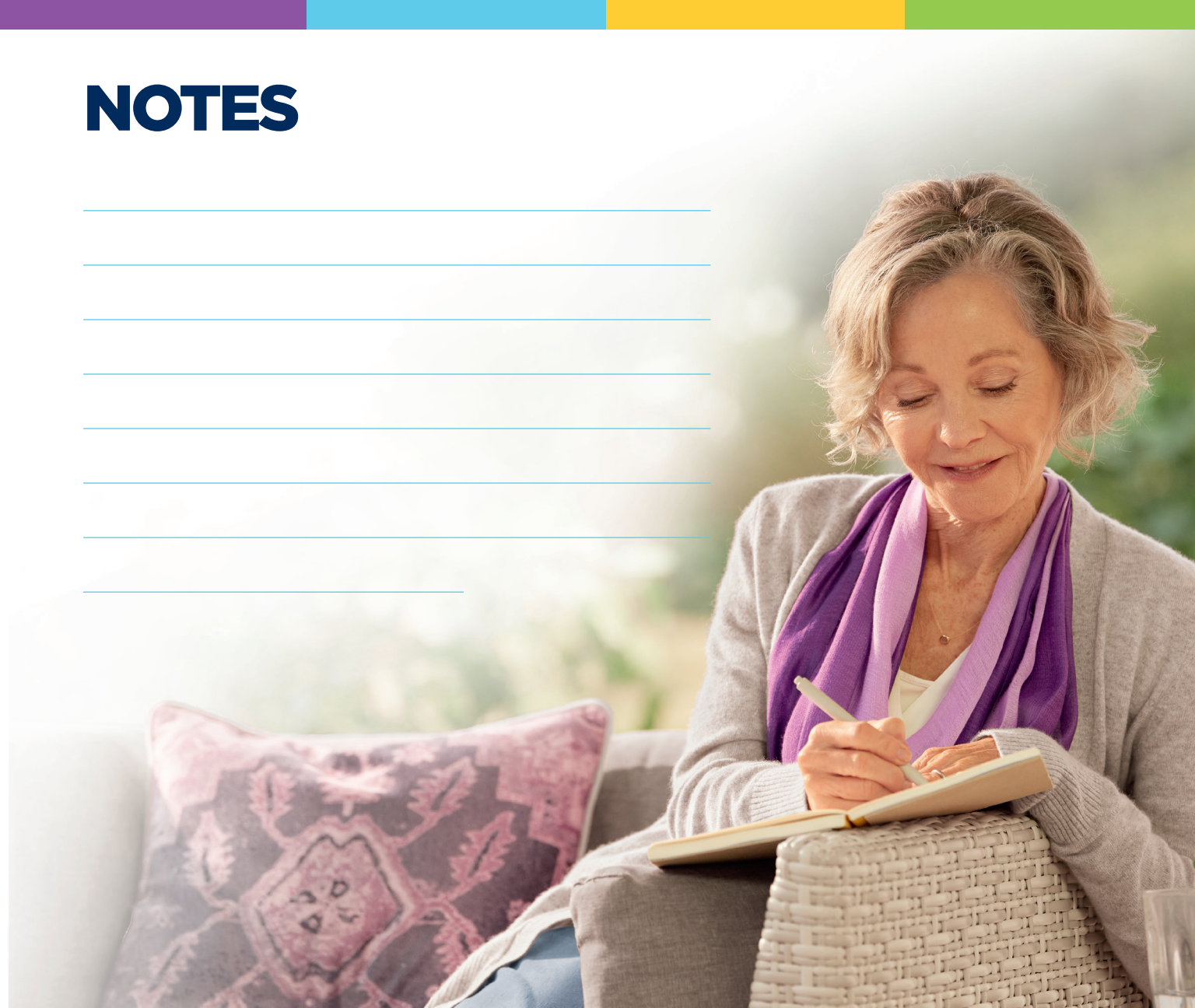
We're here for you throughout your treatment

From helping you understand coverage options to identifying available financial assistance, Takeda Oncology Here2Assist® is committed to offering you comprehensive support throughout your treatment journey.


- ▶ Works with your insurance company to help you get started on your medication
- ▶ Identifies available financial assistance that may be right for you
- ▶ Connects you to additional support services and resources
- ▶ Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- ▶ Conducts regular follow-up calls with you

Call 1-844-817-6468 or go to www.Here2Assist.com to learn more

NOTES



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

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CLAIM MORE OF YOUR LIFE



Treatment plans are a team decision.
Your voice matters. **Talk with your doctor.**

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
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ONCOLOGY

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