

The first FDA-approved chemotherapy-free* regimen

in RAS wild-type, HER2+ metastatic colorectal cancer

TUKYSA is a prescription medicine used with the medicine trastuzumab to treat adults with RAS wild-type human epidermal growth factor receptor-2 (HER2) positive colorectal cancer that has spread to other parts of the body (metastatic), or cannot be removed by surgery, and who have received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and it did not work or is no longer working.

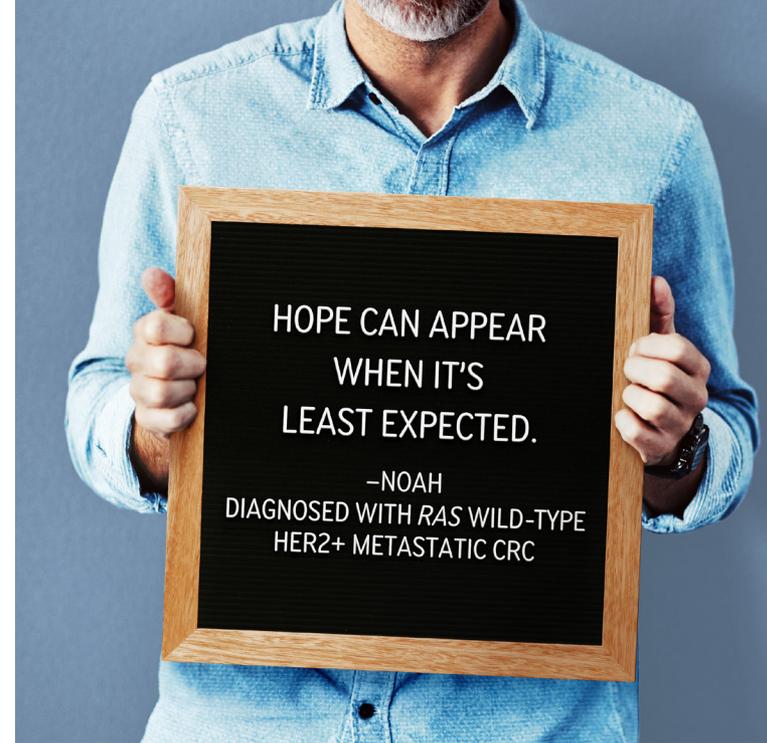
This use is approved based on a clinical study that measured how many patients had a tumor response and how long that response lasted. Studies are ongoing to confirm the benefit of TUKYSA for this use.

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

*Although they are not chemotherapy, HER2-targeted therapies can affect normal cells and cause side effects, some of which may be serious.

Select Important Safety Information

- TUKYSA may cause serious side effects that can sometimes be severe including diarrhea, liver problems, or harm to unborn babies.
- Tell your healthcare provider if you have a change in your bowel movements or severe diarrhea, or any signs and symptoms of liver problems including itching, yellowing of your skin or eyes, dark or brown urine (tea-colored), pain in the right upper stomach area (abdomen), feeling very tired, decreased appetite, or bleeding or bruising more easily than normal.
- Use effective birth control as directed. Tell your healthcare provider about all of your medical conditions, including if you are pregnant or plan to become pregnant or are breastfeeding (nursing) or plan to breastfeed.
- These are not all the possible side effects of TUKYSA.



Please see [Important Safety Information](#) throughout and accompanying [Important Facts about TUKYSA](#).

MY CARE TEAM

Oncologist: _____

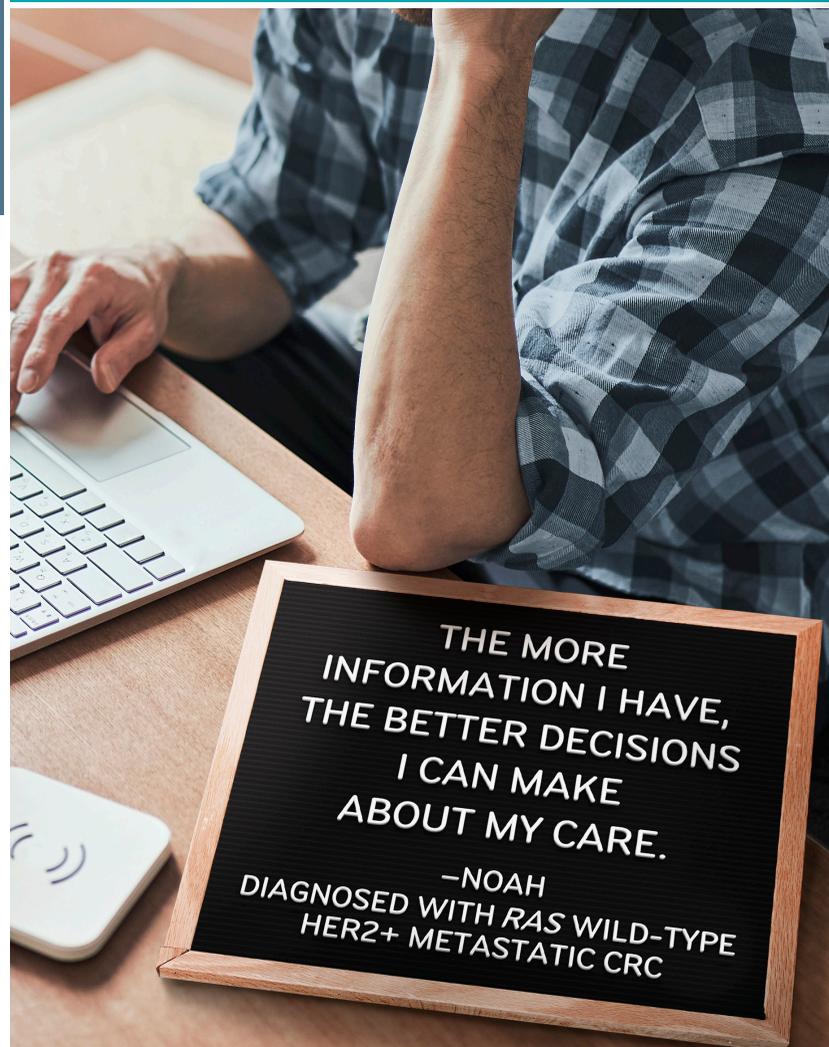
Phone number: _____

Nurse: _____

Phone number: _____

Specialty pharmacy: _____

Phone number: _____



Getting started

Learning about *RAS* wild-type, HER2 positive (HER2+) metastatic (also known as stage 4) colorectal cancer and its treatment can be a lot to take in. This brochure can help answer questions you or your loved ones may have.

This brochure should not be used instead of your healthcare provider's advice. Talk with your healthcare provider if you have questions about your cancer or your treatment.



Inside, you'll find information about:

- Select biomarkers in metastatic colorectal cancer
- Possible side effects
- Benefits with TUKYSA
- Taking TUKYSA
- Support

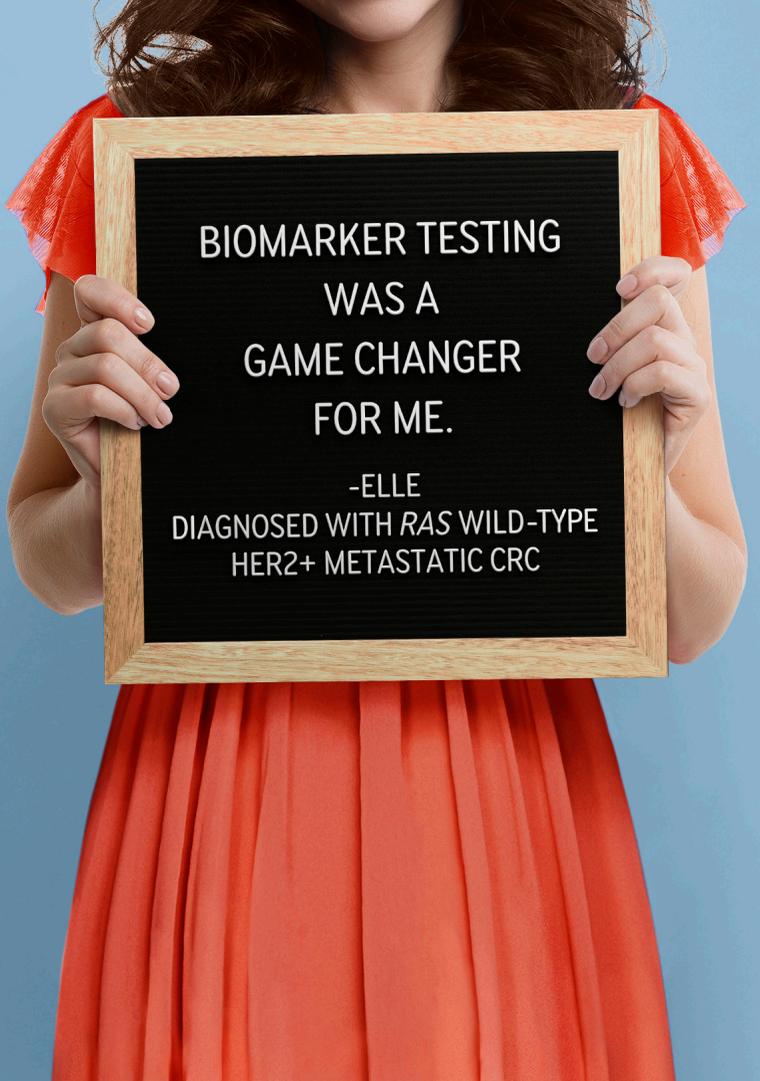
Select Important Safety Information

What are the possible side effects of TUKYSA?

TUKYSA may cause serious side effects, including:

- **Diarrhea** (watery, loose, or frequent stools) is common and can sometimes be severe. Tell your healthcare provider if you have a change in your bowel movements or severe diarrhea. Severe diarrhea can cause a loss of too much body fluids (dehydration), low blood pressure, kidney problems, and death. Your healthcare provider may prescribe medicines to treat your diarrhea during treatment with TUKYSA.





BIOMARKER TESTING
WAS A
GAME CHANGER
FOR ME.

-ELLE
DIAGNOSED WITH RAS WILD-TYPE
HER2+ METASTATIC CRC

Knowing what type of metastatic colorectal cancer you have matters

Biomarkers can help identify your type of colorectal cancer

There are different types of colorectal cancer. Each type has different biomarkers. Some biomarkers can be **proteins** found in cancer cells. They are identified by testing tumor tissue.

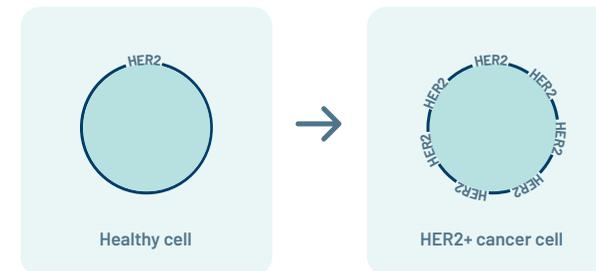


Proteins are substances that help the cells in the body work.

HER2 is an important biomarker for metastatic colorectal cancer

What is HER2?

HER2 is a protein. In healthy cells, HER2 tells cells to grow and multiply at a normal rate.



Some cancer cells have too many HER2 proteins (HER2+). Having a lot of HER2 can tell cancer cells to grow and multiply quickly.



Why does knowing my HER2 status matter?

Your HER2 status can help your healthcare provider decide what treatments may be right for you.

Select Important Safety Information (continued)

- **Liver Problems**, including severe cases. Your healthcare provider will test your blood to check your liver function before starting and every 3 weeks during treatment with TUKYSA, or as needed. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including itching, yellowing of your skin or eyes, dark or brown urine (tea-colored), pain in the right upper stomach area (abdomen), feeling very tired, decreased appetite, or bleeding or bruising more easily than normal.



The first FDA-approved chemotherapy-free* regimen in RAS wild-type, HER2+ unresectable or metastatic colorectal cancer

TUKYSA is an oral treatment designed to target HER2. It is taken with another medicine called trastuzumab (also called Herceptin®).

TUKYSA is for adults with RAS wild-type, HER2 positive colorectal cancer that has spread to other parts of the body (metastatic), or cannot be removed by surgery, and who have received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and it did not work or is no longer working.

It was first approved in 2020 for a different patient population. Visit [TUKYSA.com](https://www.tukyasa.com) to learn more.

*Although they are not chemotherapy, HER2-targeted therapies can affect normal cells and cause side effects, some of which may be serious.

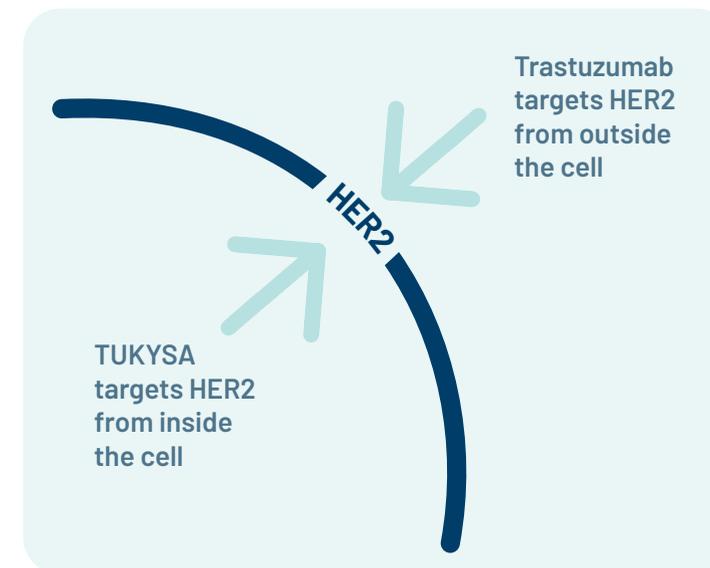
Please see [Important Safety Information throughout and accompanying Important Facts about TUKYSA.](#)



What is RAS wild type?

Like HER2, RAS is a biomarker. Sometimes RAS has a defect (also called a mutation) and sometimes it does not. When RAS does not have a defect, it is called RAS wild type (RAS WT). To be eligible for TUKYSA, you must have tumors that are both RAS wild type and HER2+.

Target HER2 from inside and out



TUKYSA and trastuzumab are not chemotherapy.

Both medicines are designed to target HER2, but they do it in different ways. Together, they may work to more completely block the signal that tells cancer cells to grow.

HER2 is also found on normal cells. This means HER2-targeted therapies can affect normal cells and cause side effects, some of which may be serious.

Select Important Safety Information (continued)

The most common side effects of TUKYSA in combination with trastuzumab in adults with RAS wild-type HER2-positive colorectal cancer include:

- diarrhea
- nausea
- infusion-related reactions
- tiredness
- stomach-area (abdomen) pain
- fever
- rash

Your healthcare provider may change your dose of TUKYSA, temporarily stop, or permanently stop treatment with TUKYSA if you have certain side effects.

TUKYSA[®]
tucatinib
50 mg | 150 mg tablets

TUKYSA was studied in a clinical trial called MOUNTAINEER



MOUNTAINEER included 84 people with RAS wild-type, HER2+ colorectal cancer that could not be removed by surgery (unresectable) or had spread to other parts of the body (metastatic).

To participate in this study, these adults must have:

- Previously received fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (some patients had also received immunotherapy)
- Had tumors that were both RAS wild type and HER2+
- Never received any therapy that targets HER2

The trial only studied people receiving TUKYSA and trastuzumab. Because they were not directly compared to people receiving any other treatment for RAS wild-type, HER2+ metastatic colorectal cancer, no conclusions can be drawn about relative effectiveness of TUKYSA + trastuzumab and other treatments.

Select Important Safety Information (continued)

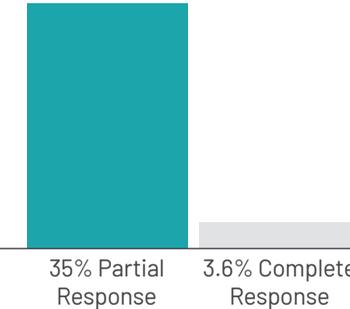
TUKYSA may cause fertility problems in males and females, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of TUKYSA. Discuss side effects with your healthcare provider. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/Safety/MedWatch.

With TUKYSA,* some people saw their tumors shrink

TUKYSA + trastuzumab

38%
OVERALL RESPONSE
(32 of 84 patients)
saw their tumors **shrink**



- **Tumors shrink**, or “partial response,” means that the amount of cancer in the body, or the size of the tumor, decreased after treatment
- **Tumors disappear**, or “complete response,” means that all signs of cancer were gone after treatment. This doesn’t mean that cancer was cured
- **Overall response** rate is the percentage of patients whose cancer shrinks or disappears after treatment

TUKYSA + trastuzumab will not work for everyone. Individual results may vary.

How long did patients respond to TUKYSA + trastuzumab treatment?

Another outcome that was measured in the clinical trial in patients who responded to treatment was the **duration of response (DOR)**. This is the length of time that tumors continued to respond to treatment. The clinical trial also measured the median DOR. **Median** is defined as the middle number in a group of numbers arranged from lowest to highest.

For the 32 of 84 patients who responded to treatment in the clinical trial:

12.4 months Median duration of response

*The TUKYSA regimen includes trastuzumab. The TUKYSA regimen may not work for everyone.

Please see **Important Safety Information** throughout and accompanying **Important Facts about TUKYSA**.



Possible side effects

Serious side effects

- 22% of people treated with TUKYSA and trastuzumab had serious **side effects**
- The most common serious side effects were blockage of the intestine, urinary tract infection, pneumonia, stomach-area (abdomen) pain, and tear (perforation) in the rectum

Common side effects



Diarrhea



Tiredness



Rash



Nausea



Stomach-area
(abdomen) pain



Infusion-related
reactions



Fever

- These are not all the possible side effects of TUKYSA and trastuzumab
- Nearly everyone in the trial had some side effects
- TUKYSA may cause fertility problems in males and females, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility



Possible symptoms of **infusion-related reactions** are itching, rash, fever, chills, redness in the face or neck, and swelling of the tongue, lips, or eyelids.

Be sure to tell your healthcare provider about any side effects you have. They may be able to help you find ways to manage them. Your healthcare provider may change your dose of TUKYSA, temporarily stop, or permanently stop treatment with TUKYSA if you have certain side effects.

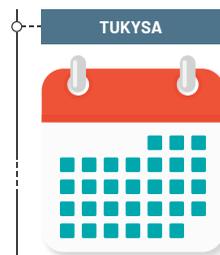


Side effects are unwanted reactions to a drug. Common side effects are those that happen often and to many people. Some side effects may be serious and require emergency medical care.

NOTES

TUKYSA is part of a **chemotherapy-free*** treatment regimen

TUKYSA is taken with another medicine called **trastuzumab**



- Take each dose about 12 hours apart and at the same times every day
- Take TUKYSA with or without food
- Swallow TUKYSA tablets whole. Do not chew, crush, or split TUKYSA tablets before swallowing. Do not take TUKYSA tablets if they are broken, cracked, or damaged
- If you vomit or miss a dose of TUKYSA, take your next dose at your regular time
- Your healthcare provider may change your dose of TUKYSA if needed



- Trastuzumab is given **intravenously** every 21 days
- Receive trastuzumab at your healthcare provider's office or infusion center on Day 1, and again every 21 days



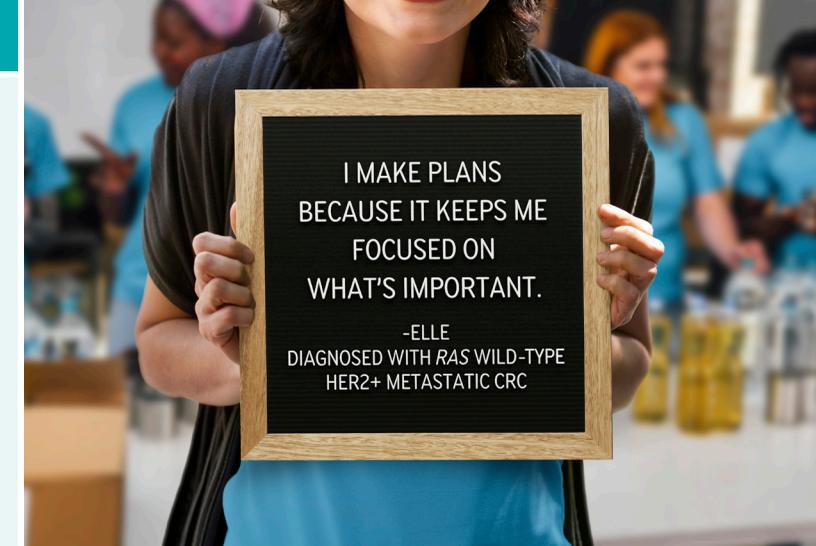
Intravenously means that the medicine is given by a needle or tube inserted into a vein.

*Although they are not chemotherapy, HER2-targeted therapies can affect normal cells and cause side effects, some of which may be serious.

Please see **Important Safety Information** throughout and accompanying **Important Facts about TUKYSA**.

Take TUKYSA exactly as your healthcare provider tells you.

Information on this page is from the TUKYSA Prescribing Information for guidance. It may be different from what your healthcare provider told you. Be sure to talk to your healthcare provider or pharmacist if you have any questions about taking TUKYSA or your dosing.



Select Important Safety Information (continued)

What should I tell my healthcare provider before taking TUKYSA?

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

- have liver problems.
- are pregnant or plan to become pregnant. TUKYSA can harm your unborn baby.

Females who can become pregnant: Your healthcare provider will do a pregnancy test before you start taking TUKYSA. Use effective birth control (contraception) during TUKYSA treatment and for 1 week after the last dose of TUKYSA. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with TUKYSA.

Males with a female partner who can become pregnant: Use effective birth control during TUKYSA treatment and for 1 week after the last dose of TUKYSA.





Tips for staying on track with your treatment



Keep track of your doses

TUKYSA is taken twice a day, 12 hours apart. Set an alarm or use a tracker to remember your AM and PM doses.



Plan ahead

TUKYSA does not need to be refrigerated and can be taken on the go. Be sure to keep TUKYSA tablets at room temperature, 68°F to 77°F (20°C to 25°C), and in the original bottle. This bottle contains a drying agent (called a desiccant) that protects the tablets from moisture. Do not throw away the drying agent. Tightly close the bottle after you take your dose.



Keep a journal

Keep a journal of how you feel. You can use your phone or the notes sections in this brochure. Bring the journal to your appointments. It may help as you talk with your healthcare provider about your treatment.

NOTES



Select Important Safety Information (continued)

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

- are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed during treatment with TUKYSA and for 1 week after the last dose of TUKYSA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TUKYSA may affect the way your other medicines work, and other medicines may affect the way TUKYSA works. Keep a list of all the medicines you take and show it to your healthcare provider and pharmacist every time you get a new medicine.



TUKYSA can be sent to you by a specialty pharmacy

There are many specialty pharmacies who understand the unique needs of people living with cancer.



Your specialty pharmacy will contact your insurance carrier to determine your prescription coverage

- Your specialty pharmacy will work with your insurance carrier to confirm coverage for your TUKYSA prescription
- If coverage has been confirmed, your specialty pharmacy will call you to coordinate how you'll receive TUKYSA and to collect any additional information needed



Your specialty pharmacy will send your medication to your home, office, or other location of your choice

- Your specialty pharmacy will need to ensure that someone will be at the delivery location to receive the package
- Your shipping address, insurance coverage, and financial responsibility must be confirmed each time your prescription is filled



Calls from your specialty pharmacy are important

- Keep in mind that these calls may come from an 800 number, the specific area code of your specialty pharmacy, or a blocked, unavailable, or unknown number on your caller ID
 - Your specialty pharmacy will leave a voicemail asking you to return their call, but because of privacy laws, they may not provide a lot of detail regarding the reason for their call
- Your specialty pharmacy will call you at least 7 days before refilling your prescription—and you can also call to ask about prescription refills



A dedicated team from your specialty pharmacy may connect with you to:

- Offer support
- Answer questions about treatment
- Guide you to resources

Your dedicated team will call you regularly when you first start treatment and will update your healthcare team about your treatment experience.



NOTES





ADVOCACY GROUPS

Many groups are available to help support people with colorectal cancer and their families. Each group offers its own range of services. Visit the websites listed here to learn more about some of these groups.

Please note that the information that follows has been provided by each of the listed groups. Pfizer is not responsible for their content, and inclusion in this brochure is not intended as an endorsement of the group or the services offered.

CancerCare

Provides free professional support services and information to help people manage the emotional, practical, and financial challenges of cancer.

cancercares.org | Helpline: 800-813-4673

Cancer Support Community

Provides free support and navigation services and educational and digital resources to patients and families whose lives have been disrupted by cancer. They also administer a toll-free helpline, as well as conduct research and advocate for policies.

cancersupportcommunity.org

Colontown

Offers a private online community for colorectal cancer patients, survivors, and care partners. There are separate neighborhoods focused on patients with different stages of disease, the differing types of treatment, and special interests. Each neighborhood is nurtured by a neighborhood host living the experience themselves.

colontown.org

Colorectal Cancer Alliance

Navigates patients and caregivers through everything they need throughout their colorectal cancer journey, from screening through survivorship, through a Helpline, Buddy Program®, patient education, online communities, trial matching, assistance programs, and more.

ccalliance.org | Helpline: 877-422-2030

Fight Colorectal Cancer

Fights colorectal cancer and serves as a relentless champion of hope for all affected by this disease through informed patient support, impactful policy change, and breakthrough research endeavors.

fightcolorectalcancer.org

Global Colon Cancer Association

Provides education about colon cancer, including information about biomarkers, treatments, and clinical trials. In addition, GCCA connects patients and caregivers around the world with local resources. Their patient advocacy toolkit supports individuals who wish to create new patient advocacy organizations in developing areas where none currently exist.

globalcca.org



Important Safety Information

What are the possible side effects of TUKYSA?

TUKYSA may cause serious side effects, including:

- **Diarrhea** (watery, loose, or frequent stools) is common and can sometimes be severe. Tell your healthcare provider if you have a change in your bowel movements or severe diarrhea. Severe diarrhea can cause a loss of too much body fluids (dehydration), low blood pressure, kidney problems, and death. Your healthcare provider may prescribe medicines to treat your diarrhea during treatment with TUKYSA.
- **Liver Problems**, including severe cases. Your healthcare provider will test your blood to check your liver function before starting and every 3 weeks during treatment with TUKYSA, or as needed. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including itching, yellowing of your skin or eyes, dark or brown urine (tea-colored), pain in the right upper stomach area (abdomen), feeling very tired, decreased appetite, or bleeding or bruising more easily than normal.

The most common side effects of TUKYSA in combination with trastuzumab in adults with RAS wild-type HER2-positive colorectal cancer include:

- diarrhea
- tiredness
- rash
- nausea
- stomach-area (abdomen) pain
- infusion-related reactions
- fever

Your healthcare provider may change your dose of TUKYSA, temporarily stop, or permanently stop treatment with TUKYSA if you have certain side effects.

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

These are not all the possible side effects of TUKYSA. Discuss side effects with your healthcare provider. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/Safety/MedWatch.

What should I tell my healthcare provider before taking TUKYSA?

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

- have liver problems.
- are pregnant or plan to become pregnant. TUKYSA can harm your unborn baby.

Females who can become pregnant: Your healthcare provider will do a pregnancy test before you start taking TUKYSA. Use effective birth control (contraception) during TUKYSA treatment and for 1 week after the last dose of TUKYSA. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with TUKYSA.

Males with a female partner who can become pregnant: Use effective birth control during TUKYSA treatment and for 1 week after the last dose of TUKYSA.

- are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed during treatment with TUKYSA and for 1 week after the last dose of TUKYSA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TUKYSA may affect

the way your other medicines work, and other medicines may affect the way TUKYSA works. Keep a list of all the medicines you take and show it to your healthcare provider and pharmacist every time you get a new medicine.

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Indication

What is TUKYSA?

TUKYSA is a prescription medicine used with the medicine trastuzumab to treat adults with RAS wild-type human epidermal growth factor receptor-2 (HER2) positive colorectal cancer that has spread to other parts of the body (metastatic), or cannot be removed by surgery, **and** who have received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and it did not work or is no longer working.

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

Please see accompanying Important Facts about TUKYSA.





Get to know TUKYSA

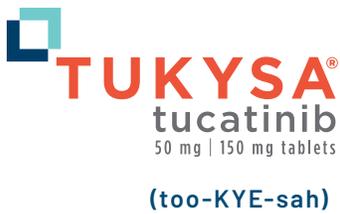
Talk with your healthcare provider to see if TUKYSA may be right for you.

Visit [TUKYSA.com](https://www.tukyasa.com) to learn more about treatment and download resources.



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IMPORTANT FACTS

This is only a brief summary of important information about TUKYSA. Talk to your healthcare provider or pharmacist to learn more.

ABOUT TUKYSA

TUKYSA is a prescription medicine used to treat adults with:

- a type of breast cancer called human epidermal growth factor receptor-2 (HER2) positive breast cancer. TUKYSA is used with the medicines trastuzumab and capecitabine, when your cancer has spread to other parts of the body such as the brain (metastatic), or cannot be removed by surgery, **and** you have received one or more anti-HER2 breast cancer treatments.
 - a type of colorectal cancer called RAS wild-type HER2 positive colorectal cancer. TUKYSA is used with the medicine trastuzumab, when your cancer has spread to other parts of the body (metastatic), or cannot be removed by surgery, **and** you have received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and it did not work or is no longer working.
- It is not known if TUKYSA is safe and effective in children.

Important information: If your healthcare provider prescribes TUKYSA in combination with capecitabine for your breast cancer, also read the Patient Information that comes with capecitabine.

BEFORE TAKING TUKYSA

Tell your healthcare provider about all your medical conditions, including if you:

- have liver problems
- are pregnant or plan to become pregnant. TUKYSA can harm your unborn baby

Women who can become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with TUKYSA
- Use effective birth control (contraception) during treatment with TUKYSA and for 1 week after the last dose of TUKYSA. Talk to your healthcare provider about birth control methods that you can use during this time
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with TUKYSA

Men with women partners who can become pregnant should use effective birth control during treatment with TUKYSA and for 1 week after the last dose of TUKYSA

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with TUKYSA and for 1 week after the last dose of TUKYSA

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- TUKYSA may affect the way your other medicines work, and other medicines may affect the way TUKYSA works
- Keep a list of all the medicines you take and show it to your healthcare provider and pharmacist every time you get a new medicine

HOW TO TAKE TUKYSA

- Take TUKYSA 2 times a day, with or without a meal.
- Take TUKYSA about 12 hours apart or at the same times every day.
- Swallow TUKYSA tablets whole. Do not chew, crush, or split TUKYSA tablets before swallowing. Do not take TUKYSA tablets if they are broken, cracked, or damaged.
- If you vomit or miss a dose of TUKYSA, take your next dose at your regular time.

POSSIBLE SIDE EFFECTS OF TUKYSA

TUKYSA may cause serious side effects, including:

- **Diarrhea.** Diarrhea is common with TUKYSA and can sometimes be severe. Tell your healthcare provider if you have a change in your bowel movements or severe diarrhea. Severe diarrhea can lead to loss of too much body fluids (dehydration), low blood pressure, kidney problems and death. Your healthcare provider may prescribe medicines to treat your diarrhea during treatment with TUKYSA.
- **Liver Problems.** TUKYSA can cause severe liver problems. Your healthcare provider will do blood tests to check your liver function before and every 3 weeks during treatment with TUKYSA, or as needed. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including:
 - itching
 - yellowing of your skin or eyes
 - dark or brown urine (tea-colored)
 - pain in the upper right side of your stomach-area (abdomen)
 - feel very tired
 - decreased appetite
 - bleeding or bruising more easily than normal

The most common side effects of TUKYSA in combination with trastuzumab and capecitabine in adults with HER2 positive breast cancer include:

- diarrhea
- rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet
- nausea
- increased liver function blood tests
- vomiting
- mouth sores (stomatitis)
- decreased appetite
- low red blood cell counts (anemia)
- rash

The most common side effects of TUKYSA in combination with trastuzumab in adults with RAS wild-type HER2 positive colorectal cancer include:

- diarrhea
- tiredness
- rash
- nausea
- stomach-area (abdomen) pain
- infusion-related reactions
- fever

Your healthcare provider may change your dose of TUKYSA, temporarily stop, or permanently stop treatment with TUKYSA if you have certain side effects.

TUKYSA may cause fertility problems in males and females, which may affect the 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 TUKYSA. Call your healthcare provider for medical advice about side effects.

GET MORE INFORMATION

- This is only a brief summary of important information about TUKYSA. Talk to your healthcare provider or pharmacist to learn more
- Go to [TUKYSA.com](https://www.tukyasa.com) for information written for healthcare professionals called the full Prescribing Information
- If you need help paying for your medicine, visit www.SeagenSecure.com for program information

