Your guide to understanding how

TUKYSA treats HER2+ metastatic breast cancer

TUKYSA is a prescription medicine used with the medicines trastuzumab and capecitabine to treat adults with human epidermal growth factor receptor-2 (HER2) positive breast cancer that has spread to other parts of the body such as the brain (metastatic), or that cannot be removed by surgery, **and** who have received one or more anti-HER2 breast cancer treatments.

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

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.

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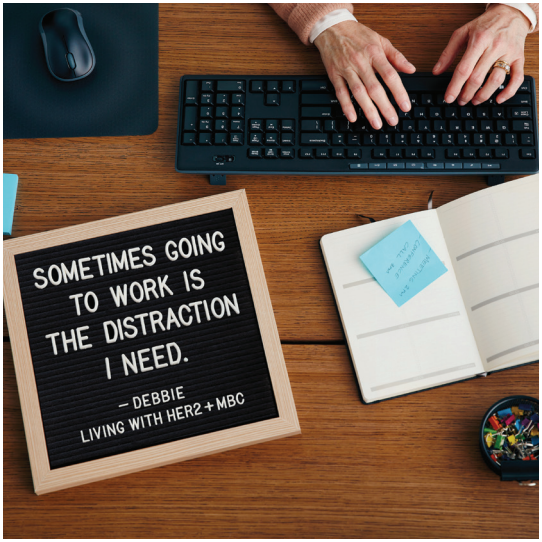
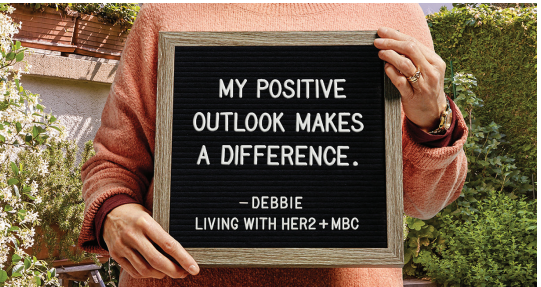
tucatinib
50 mg | 150 mg tablets



SPEAKING FROM EXPERIENCE

See what others have to say about living with HER2+ MBC

MBC = metastatic breast cancer.



Your experience is unique

As you get ready to start treatment, you may have questions or want to learn more about TUKYSA. While this brochure is designed to help you better understand TUKYSA, it should not be used in place of your healthcare provider's advice. If you have questions about your cancer or treatment plan, be sure to talk with your healthcare provider.

Inside, you'll find information on the following topics:

- About TUKYSA
- How the TUKYSA treatment plan may help you
- Possible side effects
- How TUKYSA is taken
- Starting 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.

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

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Another chance at treating your cancer

TUKYSA is a targeted oral treatment option taken with Herceptin® (trastuzumab) and Xeloda® (capecitabine). It's for people with **HER2+ metastatic breast cancer** who have received one or more anti-HER2 breast cancer treatments, such as trastuzumab, Perjeta® (pertuzumab), or Kadcyla® (trastuzumab emtansine), in the metastatic setting.

Target HER2 in 2 ways

You may have taken trastuzumab before. But when TUKYSA is taken with trastuzumab, they work together to offer another chance to slow the progression of cancer and may help you live longer.

Trastuzumab targets HER2 from outside the cell

Both TUKYSA and trastuzumab are designed to target HER2, but they do it in different ways. More than either therapy alone, together TUKYSA and trastuzumab 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.

Throughout the brochure you will see bolded words in **teal**. These are glossary terms and their definitions can be found on page 11.

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

TUKYSA® tucatinib 50 mg | 150 mg tablets

TUKYSA was evaluated in a clinical study called HER2CLIMB

Who was in the study

- Adults living with HER2+ breast cancer that could not be removed by surgery or had spread somewhere in the body such as their liver, lungs, bones, and/or brain
- Adults with different types of brain metastases, including those that were growing when the person entered the study
- Adults who had been previously treated with Herceptin® (trastuzumab), Perjeta® (pertuzumab), and Kadcyla® (trastuzumab emtansine)

How many adults were in the study

- 612 adults were enrolled in the study, of whom the first 480 were assessed for the primary endpoint of progression-free survival
- 48% (291 of the 612 adults) had brain metastases when they entered the study
- Among the adults with brain metastases:
  - 40% had stable brain metastases, which means they were not growing or spreading
  - 60% had active brain metastases, which means they were growing or spreading

The treatment they received

- Adults were randomly assigned to a treatment group:
  - 410 adults received treatment with TUKYSA, along with trastuzumab and capecitabine
  - 202 adults received treatment with trastuzumab and capecitabine alone

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.

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

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As demonstrated in the HER2CLIMB study

TUKYSA* has been proven to offer more time without the cancer growing or spreading

- In the clinical study, the **median** amount of time people lived without cancer progressing was 7.8 months with TUKYSA, along with trastuzumab and capecitabine, versus 5.6 months with trastuzumab and capecitabine alone†

Median is defined as the middle number in a group of numbers arranged from lowest to highest.

Over the course of the trial, the TUKYSA* regimen led to

46% REDUCTION

in the chance of disease progression or death, compared to the control arm

*TUKYSA is part of a treatment plan that includes trastuzumab and capecitabine.

†Studied in 320 people who received TUKYSA, along with trastuzumab and capecitabine, and in 160 people who received trastuzumab and capecitabine alone.

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

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In the HER2CLIMB study, TUKYSA helped people live longer

Median overall survival

People lived, on average, 4.5 months longer when TUKYSA was included in their regimen.

TUKYSA + trastuzumab + capecitabine*
21.9 MONTHS

VS

Placebo + trastuzumab + capecitabine*
17.4 MONTHS

4.5 MONTHS LONGER

As a follow-up analysis, per protocol, a pre-specified analysis was performed 24 months after the last person was enrolled.

Results depicted below from this follow-up analysis are exploratory. This means the study was not designed to find differences between the two groups at that time point. Please interpret with caution.

Median overall survival at follow-up (exploratory analysis)

TUKYSA + trastuzumab + capecitabine*
24.7 MONTHS

Placebo + trastuzumab + capecitabine*
19.2 MONTHS

*Studied in 410 people who received TUKYSA + trastuzumab + capecitabine and in 202 people who received placebo + trastuzumab + capecitabine alone.

Select Important Safety Information (continued)

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
- a low number of red blood cells (anemia)
- rash

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

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

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

As demonstrated in the HER2CLIMB study

TUKYSA* offered more time without cancer growing or spreading in people with brain metastases

- In the clinical study, the **median** amount of time that cancer did not grow or spread in people living with brain metastases was 7.6 months with TUKYSA, along with trastuzumab and capecitabine, versus 5.4 months with trastuzumab and capecitabine alone†

  Median is defined as the middle number in a group of numbers arranged from lowest to highest.

Over the course of the trial, the TUKYSA* regimen led to

52% REDUCTION

in the chance of disease progression or death for patients with brain metastases, compared to the control arm

*TUKYSA is a part of a treatment plan that includes trastuzumab and capecitabine.

†Studied in 198 people with brain metastases who received TUKYSA, along with trastuzumab and capecitabine, and in 93 people with brain metastases who received trastuzumab and capecitabine alone.

Visit TUKYSA.com to learn more.

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 negative side effects to the FDA at 1-800-FDA-1088 or **www.fda.gov/Safety/MedWatch**.

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

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Possible side effects

Serious side effects

- 26% of people treated with TUKYSA, along with trastuzumab and capecitabine, had serious **side effects**
  - The most common serious side effects were diarrhea, vomiting, nausea, abdominal pain, and seizure

Common side effects

The most common side effects were:


Diarrhea


Increased liver function blood tests


Decreased appetite


Rash, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet


Vomiting


A low number of red blood cells (anemia)


Nausea


Mouth sores (stomatitis)


Rash

- These are not all the possible side effects of TUKYSA, and you may also get side effects from the other medicines taken with TUKYSA
- Nearly everyone in the trial had some side effects
- People in the TUKYSA clinical study were not required to take an antidiarrheal medicine
- **Hair loss was not common in people in either of the two treatment groups (4.7% of people treated with TUKYSA, along with trastuzumab and capecitabine, had hair loss versus 3.6% of people treated with trastuzumab and capecitabine alone) in the clinical study**
- 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

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

TUKYSA® tucatinib 50 mg | 150 mg tablets

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.

Glossary

HER2+ metastatic breast cancer: A type of breast cancer where there is more HER2 on the surface of the cancer cells than on healthy breast cells, and the cancer has spread to other parts of the body

Median: The middle number in a group of numbers that are listed from lowest to highest; also called the midpoint

Overall survival: A measure of how long people live once starting a clinical study

Side effects: 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

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

TUKYSA® tucatinib
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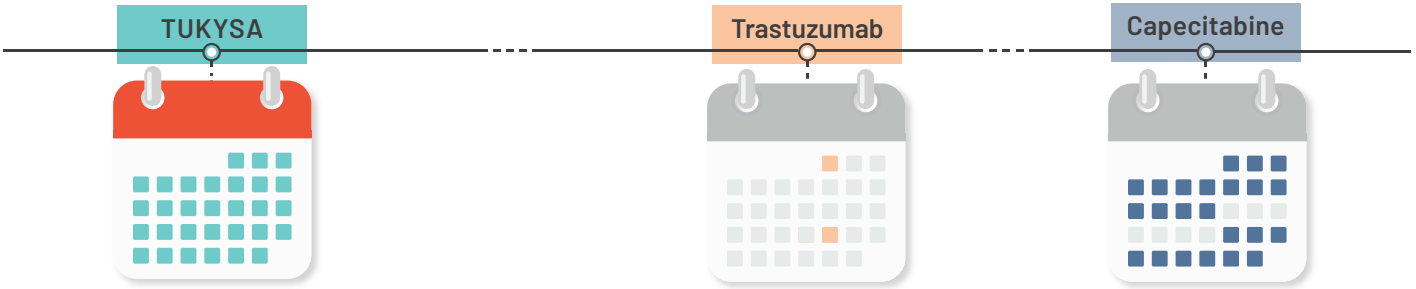
Here's how TUKYSA is taken

TUKYSA is part of a treatment plan that includes Herceptin® (trastuzumab) and Xeloda® (capecitabine).



- Take each dose about 12 hours apart and at the same times every day
- Take TUKYSA with or without food
- Swallow tablets whole. Do not chew, crush, or split the tablets. 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

- Receive trastuzumab at your healthcare provider's office or infusion center on Day 1 and again every 21 days

- Take orally, twice daily, within 30 minutes after a meal
- TUKYSA and capecitabine can be taken at the same time
- Take capecitabine for 14 days, with a 7-day break before starting again

The TUKYSA Treatment Tracker has more information on how to take TUKYSA and offers tools to help you start and stay on treatment as your healthcare provider has recommended. The tracker is included in your starter kit, and additional calendars can be downloaded at **TUKYSA.com**.

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

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

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 get pregnant: Use effective birth control during TUKYSA treatment and for 1 week after the last dose of TUKYSA.

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TUKYSA can be sent to you by a specialty pharmacy

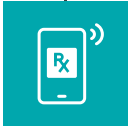
There are many specialty pharmacies who understand the unique needs of people living with cancer.

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 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

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

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.

Your TUKYSA and capecitabine may come from two different pharmacies. If you have any challenges in coordination of care or scheduling deliveries, Seagen has dedicated staff, **Seagen Secure®**, to help support you in obtaining your prescribed medicines if enrolled in the program.*

*Eligibility criteria apply. Pfizer does not guarantee that enrollment will result in assistance and/or reimbursement.

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

Select Important Safety Information (continued)

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

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

Seagen Secure®

Access.
Advocates.
Answers.

Patient Assistance & Reimbursement Support

Seagen Secure® can help you understand your insurance coverage and connect you with resources and support services to assist with accessing your prescribed TUKYSA treatment.* Seagen Secure's support offerings include an out-of-pocket assistance program to help eligible, commercially insured patients reduce their copay costs and a patient assistance program for those who qualify.

Call 855-4-SECURE
8:00 AM–8:00 PM ET Monday–Friday

Visit SeagenSecure.com

*Eligibility criteria apply. Pfizer does not guarantee that enrollment will result in assistance and/or reimbursement.

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

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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 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
- a low number of red blood cells (anemia)
- 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 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 negative side effects to the FDA at 1-800-FDA-1088 or **www.fda.gov/Safety/MedWatch**.

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

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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 get 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 medicines trastuzumab and capecitabine to treat adults with human epidermal growth factor receptor-2 (HER2) positive breast cancer that has spread to other parts of the body such as the brain (metastatic), or that cannot be removed by surgery, **and** who have received one or more anti-HER2 breast cancer treatments.

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

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

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SPEAK FOR YOURSELF

Talk with your healthcare provider to see if TUKYSA may be right for you. Visit TUKYSA.com to learn more and download additional resources.

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

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(too-KYE-sah)

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** 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

Pfizer Oncology