

Frequently Asked Questions

The information presented here is not intended to replace a discussion with your healthcare provider. If you have questions about HER2+ metastatic breast cancer or treatment with TUKYSA, please talk with your healthcare provider.

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.

Could TUKYSA be right for me?

TUKYSA was studied in 612 people with HER2+ metastatic breast cancer that had spread (metastasized) to other parts of the body, in a clinical trial called HER2CLIMB. These people had been treated before with HERCEPTIN® (trastuzumab), PERJETA® (pertuzumab), and KADCYLA® (trastuzumab emtansine).

In HER2CLIMB, people were either given:

- TUKYSA + trastuzumab + XELODA® (capecitabine)
- Trastuzumab + capecitabine alone

What can I expect from treatment with TUKYSA?

TUKYSA offers another chance at treating HER2+ metastatic breast cancer. In HER2CLIMB, treatment with TUKYSA, trastuzumab, and capecitabine was shown to:

- Offer more time without the cancer growing and spreading (*median time without progression was 7.8 months with TUKYSA along with trastuzumab and capecitabine versus 5.6 months with trastuzumab and capecitabine alone*)
- Help people live longer (*median overall survival was 21.9 months with TUKYSA along with trastuzumab and capecitabine versus 17.4 months with trastuzumab and capecitabine alone*)

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

What are the most common side effects seen with TUKYSA?

The most common side effects seen with TUKYSA:

- diarrhea
- rash, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet
- nausea
- tiredness
- increased liver function blood tests
- vomiting
- mouth sores (stomatitis)
- decreased appetite
- stomach-area (abdomen) pain
- headache
- a low number of red blood cells (anemia)
- 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.

Talk to your healthcare provider about any side effects that bother you or do not go away. See the following page for TUKYSA Important Safety Information.

How do I take TUKYSA?

TUKYSA is an oral treatment. The recommended dose of TUKYSA is 300 mg twice daily, taken 12 hours apart 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 doctor may change your dose of TUKYSA if needed.

Has TUKYSA been evaluated in people with HER2+ metastatic breast cancer that has spread to the brain?

Yes. Nearly half of all people in HER2CLIMB (291 out of 612) had brain metastases.

- This included people with untreated and treated brain metastases that were stable or progressing since their last treatment
- In this population of people with brain metastases, TUKYSA offered more time without the cancer growing and spreading (*median time without progression was 7.6 months with TUKYSA along with trastuzumab and capecitabine compared to 5.4 months with trastuzumab and capecitabine alone*)

Do I need tests with TUKYSA?

Your healthcare provider will test your blood to check your liver function before and every 3 weeks during treatment with TUKYSA, or as needed. These tests may be performed when you go in for your trastuzumab treatment. Based on the test results, your healthcare provider may adjust your dose, or temporarily or permanently stop treatment with TUKYSA.

If you are a female who can become pregnant, your healthcare provider will do a pregnancy test before starting TUKYSA.

How will I receive TUKYSA?

TUKYSA will be sent to you by a Specialty Pharmacy that has unique experience in oncology and is trained in helping people who are living with cancer to manage their treatment. Your Specialty Pharmacy offers ongoing support by:

- Coordinating your treatment plan and collaborating with your healthcare provider
- Working with your insurance provider to obtain coverage for TUKYSA
- Answering your questions about treatment
- Guiding you to resources

Are there assistance and support programs available to help access TUKYSA?

Seattle Genetics is committed to supporting people who are prescribed TUKYSA in accessing their treatment. SeaGen Secure®, a personalized support program, will help eligible people navigate out-of-pocket assistance for the cost of their therapy, provide patient assistance and coverage support, and make connections to community resources and services.

If your metastatic breast cancer has spread after at least one anti-HER2 treatment, talk with your healthcare provider to find out if TUKYSA may be right for you.

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 fluid (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 the skin or eyes, dark or brown urine (tea-colored), pain or discomfort 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:

- diarrhea
- vomiting
- rash, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet
- mouth sores (stomatitis)
- decreased appetite
- nausea
- stomach-area (abdomen) pain
- tiredness
- headache
- increased liver function blood tests
- 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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088.

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 get pregnant. TUKYSA can harm your unborn baby.

Females who are able to 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 at least 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 at least 1 week after the last dose of TUKYSA.

- are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed during treatment with TUKYSA and for at least 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.

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 accompanying Important Facts about TUKYSA.



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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 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.

Important information: Also read the capecitabine Medication Guide.

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 at least 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:

- Use effective birth control (contraception) during treatment with TUKYSA and for at least 1 week after the last dose of TUKYSA
- Are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with TUKYSA and for at least 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 food
- Take TUKYSA about 12 hours apart or at the same times every day
- Swallow TUKYSA 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

POSSIBLE SIDE EFFECTS OF TUKYSA

TUKYSA can cause serious side effects, including:

- **Diarrhea** (watery, loose, or frequent stools), which is common and can sometimes be severe
 - Severe diarrhea can lead to loss of too much body fluid (dehydration), low blood pressure, kidney problems, and death
 - Tell your healthcare provider if you have a change in your bowel movements or severe diarrhea. 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 TUKYSA and every 3 weeks during treatment with TUKYSA, or as needed.

Tell your healthcare provider right away if you have signs or symptoms of liver problems including itching, yellowing of the skin or eyes, dark or brown (tea-colored) urine, pain in the upper right side of your stomach area (abdomen), feeling very tired, decreased appetite, or bleeding or bruising more easily than normal.

The most common side effects of TUKYSA include:

- diarrhea
- vomiting
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- mouth sores (stomatitis)
- decreased appetite
- stomach-area (abdomen) pain
- nausea
- headache
- tiredness
- low red blood cell counts (anemia)
- increased liver function blood tests
- rash

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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. Call your doctor 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 www.TUKYSA.com or call 1-855-4SEAGEN
- If you need help paying for your medicine, visit www.SeaGenSecure.com for program information

