

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **TUKYSA™** tucatinib tablets

Read this carefully before you start taking **TUKYSA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TUKYSA**.

Your breast cancer will be treated with **TUKYSA** in combination with other medications (trastuzumab and capecitabine). Read the Consumer Information leaflets for those medications as well as this one.

Serious Warnings and Precautions

TUKYSA can cause severe side effects, including:

Severe diarrhea. This is when you have frequent loose or liquid bowel movements. It can cause you to become dehydrated and have severe kidney problems that could be life threatening. Your healthcare professional may give you medications to help treat diarrhea. Tell your healthcare professional right away at the first sign of diarrhea.

Hepatotoxicity. These are severe liver problems. Your healthcare professional will do blood tests to check if your liver is working properly.

Potential harm to your unborn baby. If you are female patient who is pregnant or plans to become pregnant, be aware that TUKYSA may harm your unborn baby. Females should avoid becoming pregnant while taking TUKYSA. Use effective birth control methods while taking TUKYSA and for at least 1 week after your last dose. Your healthcare professional can tell you about ways to prevent pregnancy while you are taking TUKYSA. If you become pregnant, or think you might be pregnant while taking TUKYSA, tell your healthcare professional right away.

What is TUKYSA used for?

TUKYSA is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that:

- is positive for human epidermal growth factor receptor 2 (HER2 positive),
- cannot be removed by surgery,
- has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and
- has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine.

How does TUKYSA work?

Tucatinib, the active ingredient in TUKYSA, belongs to a family of medications called kinase inhibitors. These medications work by blocking the HER2 receptors on the cancer cells. This may slow or stop cancer cells from growing or may kill them.

What are the ingredients in TUKYSA?

Medicinal ingredients: tucatinib

Non-medicinal ingredients: Colloidal silicon dioxide, copovidone, crospovidone, macrogol/polyethylene glycol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, potassium chloride, sodium bicarbonate, sodium chloride, talc, titanium dioxide, yellow iron oxide non-irradiated.

TUKYSA comes in the following dosage forms:

Tablets: 50 mg and 150 mg

Do not use TUKYSA if:

- you are allergic to tucatinib or any of the other ingredients in this medication.

Remember to read the Consumer Information leaflets for capecitabine and trastuzumab. These will help you to determine if there are other reasons why you should not be treated with this combination of medications.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TUKYSA. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have brain metastases. This is when your cancer has spread to your brain. Some brain metastases may need other treatment before TUKYSA can be started to ensure proper use.

Other warnings you should know about:

Female patients:

- If you are able to get pregnant, your doctor will do a pregnancy test before you start taking TUKYSA.
- If you are breastfeeding or planning to breastfeed: it is not known if TUKYSA passes into breast milk. You should not breastfeed while you are taking TUKYSA and for at least 1 week after your last dose. Talk to your healthcare professional about the best way to feed your baby during this time.

Male patients with female sexual partners who are pregnant, might be pregnant or could become pregnant:

- Use condoms each time you have sex while taking TUKYSA and for at least 1 week after your last dose.
- Avoid fathering a child during your treatment. If your partner becomes pregnant, tell your healthcare professional right away.
- It is not known if TUKYSA is present in semen.
- Do not donate or store semen during your treatment and for at least 1 month after your last dose of TUKYSA.

Fertility: Taking TUKYSA may affect your fertility. This means that it may be difficult for you to have a child. Talk to your healthcare professional if you have questions about this.

Palmar-Plantar Erythrodysesthesia (Hand-Foot Syndrome): Some patients taking TUKYSA have experienced hand-foot syndrome. Talk to your healthcare professional if you feel any tingling, tenderness, redness or swelling on the palm of the hand or the sole of the foot. These are signs of hand-foot syndrome.

Stomatitis: Some patients taking TUKYSA have experienced stomatitis, which is a condition that affects the inside of your mouth. Talk to your healthcare professional if you develop sores in your mouth or redness and swelling of the lining of your mouth. These are signs of stomatitis.

Blood tests:

During your treatment with TUKYSA, you will need to have blood tests. These blood tests will help your healthcare professional to know how well your liver and kidneys are working. Depending on the test results, your healthcare professional may need to lower your dose or stop your treatment with TUKYSA.

Driving and using machines: Before you do tasks that require special attention, wait until you know how you respond to TUKYSA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TUKYSA:

- A medicine used to treat bacterial and fungal infections called rifampicin
- A medicine used to treat seizures called phenytoin
- Medicines used to treat high blood pressure or heart problems such as digoxin, clopidogrel
- A medicine used to treat abnormal levels of fat in the blood called gemfibrozil
- Medicines used to treat alcohol dependence, seizures, anxiety disorders, panic, agitation, and insomnia such as midazolam, triazolam
- Medicines used to treat blood clots in your body such as dabigatran etexilate
- A medicine used to prevent and treat allergy symptoms called fexofenadine

How to take TUKYSA:

- exactly as your healthcare professional tells you.
- twice a day by mouth, with or without food. Take your doses about 12 hours apart at about the same times each day.
- swallow the tablets whole. Do not chew, crush or split the tablets before swallowing them.
- You may take your TUKYSA tablets at the same time as your capecitabine.

You will take TUKYSA with the medications trastuzumab and capecitabine. Your healthcare professional will tell you how much of these medications you will take and how you will receive them.

Usual dose: 300 mg (two 150 mg tablets) twice a day

If you have severe liver or kidney problems or are taking certain medications, you may start at

a lower dose of TUKYSA.

Your healthcare professional may interrupt, stop or lower your dose of TUKYSA. This can happen if you experience certain side effects or if your disease gets worse.

Overdose:

If you think you have taken too much TUKYSA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of TUKYSA, take your next dose at the regularly scheduled time. Do not double your dose or take extra tablets to make up the missed dose.

If you vomit after taking your TUKYSA, do not take an extra dose. Take your next dose at the usual time.

What are possible side effects from using TUKYSA?

These are not all the possible side effects you may feel when taking TUKYSA. You may also get side effects from the other medications taken with TUKYSA. If you experience any side effects not listed here, contact your healthcare professional.

- Weight loss
- Decreased appetite
- Trouble swallowing
- Abdominal pain
- Joint pain
- Chest discomfort or pain
- Flu-like illness
- Fever
- Leg swelling
- Muscle weakness
- Low energy
- Feeling sad
- Painful urination
- Accidental peeing
- Nosebleed
- Rash
- Hair loss
- Night sweats
- Open wound or sore
- Low blood pressure

TUKYSA can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	

	Only if severe	In all cases	Stop taking drug and get immediate medical help
VERY COMMON			
Diarrhea: loose, watery stools		x	
Nausea: feeling sick		x	
Vomiting: being sick		x	
Hepatotoxicity (liver problems): itching, yellowing of the skin or eyes (jaundice), dark urine, and pain or discomfort in the right upper stomach area.		x	
Stomatitis: Mouth ulcers/sores, redness and swelling of the lining of the mouth		x	
Anemia (low level of red blood cells): shortness of breath, feeling very tired, pale skin, fast heartbeat, loss of energy, weakness		x	
Peripheral neuropathy (damage to nerves): weakness, numbness and pain in hands and feet		x	
Palmar-Plantar Erythrodyesthesia (Hand-Foot Syndrome): tingling, tenderness, redness and swelling usually on the palm of the hand or the sole of the foot		x	
COMMON			
Dehydration (loss of too much fluid from the body): thirst, dry mouth, headache, decreased amount of urine, dark yellow urine		x	
Palpitations: fast heartbeat, heartbeat fluttering rapidly		x	
Rectal hemorrhage: bleeding from the rectum		x	
Seizure (convulsion): muscle twitching, changes in emotions, confusion, loss of consciousness with uncontrollable shaking			x
Vaginal hemorrhage: bleeding from the vagina		x	
UNCOMMON			

Cardiac Failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in the ankles and feet, cough nausea, rapid or irregular heartbeat			X
Septic Shock (severely low blood pressure from blood infection): fever, dizziness, chills, rapid breathing, rapid heartbeat			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store TUKYSA at 20°C to 25°C.
- Replace the cap on the bottle after each time you open it.
- 3 months after opening the bottle, any unused tablets should be discarded according to your local rules. If you are not sure, ask your pharmacist about what to do with unused medications that you no longer need.

Keep out of reach and sight of children.

If you want more information about TUKYSA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website www.seagen.com, or by calling 1-833-473-2436.

This leaflet was prepared by Seagen Inc.

TUKYSA is a trademark of Seagen Inc.

Last Revised July 8, 2021