

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using TUKYSA?

TUKYSA contains the active ingredient tucatinib. TUKYSA is used with other medicines to treat different kinds of cancers.

For more information, see Section [1. Why am I using TUKYSA?](#) in the full CMI.

### 2. What should I know before I take TUKYSA?

Do not use if you have ever had an allergic reaction to tucatinib or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take TUKYSA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TUKYSA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take TUKYSA?

- Take TUKYSA exactly as your doctor has told you. Your doctor may change your dose of TUKYSA if needed.
- The usual dose is 300 mg (two 150 mg tablets) by mouth twice a day, with or without food. Each dose of TUKYSA should be taken 12 hours apart at the same time every day.
- TUKYSA tablets should be swallowed whole. Do not chew or crush the tablet.

More instructions can be found in Section [4. How do I take TUKYSA?](#) in the full CMI.

### 5. What should I know while using TUKYSA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking TUKYSA.</li><li>• TUKYSA can cause severe diarrhoea. Tell your doctor right away at the first sign of diarrhoea.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine without talking to your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• TUKYSA is not expected to affect your ability to drive or operate machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Follow the instructions in the carton on how to take care of your medicine properly.</li><li>• Store below 25°C</li></ul>

For more information, see Section [5. What should I know while taking TUKYSA?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects of TUKYSA are diarrhoea, nausea, vomiting, mouth ulcers, rash, joint pain, weight loss, nose bleed and liver problems.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# TUKYSA<sup>®</sup> (too-kye-sah)

**Active ingredient(s):** tucatinib

TUKYSA in combination with trastuzumab has **provisional approval** in Australia for the treatment of adult patients with RAS wild-type HER2 positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TUKYSA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TUKYSA.**

**Where to find information in this leaflet:**

- [1. Why am I using TUKYSA?](#)
- [2. What should I know before I use TUKYSA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TUKYSA?](#)
- [5. What should I know while taking TUKYSA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using TUKYSA?

**TUKYSA contains the active ingredient tucatinib.**

TUKYSA works by blocking the human epidermal growth factor receptor 2 (HER2) receptors on the cancer cells. It may slow or stop cancer cells from growing or may kill them.

Adults may get TUKYSA if their cancer has spread or cannot be taken out by surgery.

Adults may get TUKYSA if their breast cancer has spread beyond the original tumour or to other organs such as the brain (locally advanced or metastatic breast cancer).

Adults get TUKYSA if they have previously received at least one prior cancer treatment.

**TUKYSA is used to treat patients who have:**

- a kind of cancer called HER2 positive breast cancer in adults
- a kind of cancer called RAS wild type HER2 positive colorectal cancer in adults

**TUKYSA is taken with other anti-cancer medicines: capecitabine and trastuzumab for breast cancer, or with trastuzumab for colorectal cancer.** Also read the information about capecitabine and trastuzumab that is contained in separate Consumer Medicine Information leaflets for those medicines. Ask your doctor for a copy.

## 2. What should I know before I take TUKYSA?

### Warnings

**Do not take TUKYSA if:**

- you are allergic to tucatinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- **have any problems with your liver.** Your doctor will run tests to check that your liver is working properly during your treatment with TUKYSA.
- **are pregnant or intend to become pregnant.** TUKYSA can cause harm to an unborn baby when administered to a pregnant woman. **Talk to your doctor before you take TUKYSA if you think you may be pregnant or are planning to have a baby.** See section "Pregnancy and breast-feeding" below.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

TUKYSA may cause harm to an unborn baby when administered to a pregnant woman. Check with your doctor if you are **pregnant**, think you **may be pregnant** or are **planning to have a baby**.

- Your doctor will do a pregnancy test before you start taking TUKYSA.
- **Use a reliable method of contraception** to avoid becoming pregnant while you are taking TUKYSA and for at least 1 week after the last dose.
- **If you are male with a female sexual partner who can become pregnant, use a reliable method of contraception** to avoid pregnancy while you are taking TUKYSA and for at least 1 week after the last dose.
- If you **become pregnant** during treatment with TUKYSA, **tell your doctor**. The doctor will assess the potential benefit to you and the risk to the unborn baby, of continuing this medicine.

It is not known whether TUKYSA passes into breast milk. **Talk to your doctor if you are breastfeeding or planning to breastfeed.** You should not breastfeed during treatment with TUKYSA and for at least 1 week after the last dose. Talk to your doctor about the best way to feed your baby during treatment if you breastfeed.

### Children and adolescents

TUKYSA has not been studied in patients under the age of 18 years. The safety of TUKYSA and how effective it is is not known for this age group.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Tell your doctor if you are taking or have recently taken any of the following medicines.** Some medicines may affect the way TUKYSA works or TUKYSA may affect how other medicines work.

- St John's Wort – a herb extract used to relieve anxiety and/or stress related symptoms
- erythromycin, itraconazole, rifabutin, rifampicin, ivermectin – medicines used to treat infections, ritonavir, darunavir, saquinavir, tipranavir, indinavir, maraviroc – medicines used to treat HIV
- phenytoin, carbamazepine – medicines used to treat seizures
- pimozide, buspirone, nisoldipine, lurasidone, quetiapine – medicines used to treat certain mental health problems
- verapamil, diltiazem, quinidine, digoxin, clopidogrel, dronedarone, eplerenone, ticagrelor, amlodipine, felodipine – medicines used to treat high blood pressure or heart problems
- atorvastatin, gemfibrozil, lomitapide, lovastatin, simvastatin – medicines used for cholesterol problems
- cimetidine, ranitidine – medicines used to treat stomach ulcers or indigestion
- leflunomide – a medicine used to treat arthritis
- methadone – a medicine used to treat pain and addiction
- dexamethasone, methylprednisolone – medicines used to treat conditions such as allergies, asthma, chronic obstructive lung disease, rheumatic problems, skin disease, swelling, and ulcerative colitis
- phenobarbital, butalbital – medicines used to treat sleeping disorders or headaches
- montelukast – a medicine used to treat asthma
- avanafil, vardenafil, sildenafil – medicines used to treat erectile dysfunction
- darifenacin – a medicine used to treat urinary incontinence
- midazolam, triazolam, alprazolam, diazepam, clonazepam – medicines used to treat alcohol dependence, seizures, anxiety disorders, panic, agitation, and insomnia
- eletriptan – a medicine used to treat migraines

- tolvaptan – medicines used to prevent the loss of water from the body by reducing urine output
- methotrexate – used to treat cancer and autoimmune diseases
- domperidone, aprepitant – medicine used to treat nausea and vomiting
- morphine – a medicine used to reduce acute and chronic pain
- colchicine – a medicine used to treat gout
- dabigatran, rivaroxaban – medicines used to treat blood clots in your body
- fexofenadine – a medicine used for allergies

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TUKYSA.**

## 4. How do I take TUKYSA?

### How much to take

- Take TUKYSA exactly as your doctor has told you
- The recommended dose is 300 mg (two 150 mg tablets) by mouth twice a day. However, your doctor may change your dose of TUKYSA if you experience certain side effects. To allow for a lower dose, your doctor may prescribe 50 mg tablets for you
- TUKYSA can be taken with or without food
- Swallow the tablets whole, one after the other. Do not chew or crush the tablet.
- Do not take an additional dose if vomiting occurs after TUKYSA administration but continue with the next scheduled dose
- Follow the instructions provided and **do not stop taking TUKYSA without talking to your doctor.**

### When to take TUKYSA

- Each dose of TUKYSA should be taken about 12 hours apart at the same times every day,

### If you forget to take TUKYSA

TUKYSA should be taken regularly at the same time each day. If you miss your dose at the usual time, **skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.**

### If you take too much TUKYSA

If you think that you have taken more TUKYSA than you should have, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking TUKYSA?

### Things you should do

- TUKYSA can cause severe diarrhoea. **Tell your doctor right away at the first sign of diarrhoea.**
- Remind any doctor, dentist or pharmacist you visit that you are taking TUKYSA.

### Things you should not do

- Do not stop taking this medicine without talking to your doctor.

### While you are on TUKYSA

- Depending on the side effects you have, your doctor may recommend lowering your dose or temporarily stopping your treatment.
- Your doctor may also carry out tests to check your liver function during treatment with TUKYSA.

### Dietary considerations

**Tell your doctor if you are on a salt or potassium-controlled diet.** TUKYSA contains 55 mg sodium per 300 mg dose, equivalent to 2.75% of the WHO recommended maximum daily intake of 2 g sodium for an adult and 60.58 mg potassium per 300 mg dose.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how TUKYSA affects you.**

TUKYSA is not expected to affect your ability to drive or operate machines. However, you are responsible to decide if you can drive a motor vehicle or perform other tasks that require increased concentration.

### Looking after your medicine

- Store below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal related</b></p> <ul style="list-style-type: none"> <li>• nausea</li> <li>• vomiting</li> <li>• mouth sores, inflammation of the mouth, mouth ulcers</li> <li>• stomach-area (abdomen) pain</li> </ul> <p><b>Skin related</b></p> <ul style="list-style-type: none"> <li>• rash</li> <li>• rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet</li> </ul> <p><b>Muscles and joint related</b></p> <ul style="list-style-type: none"> <li>• joint pain</li> </ul> <p><b>Liver Related</b></p> <ul style="list-style-type: none"> <li>• increased liver function blood tests</li> </ul> <p><b>Blood Related</b></p> <ul style="list-style-type: none"> <li>• decrease in red blood cell count</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>• weight loss</li> <li>• decreased appetite</li> <li>• tiredness</li> <li>• headache</li> <li>• nosebleed</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Gastrointestinal related</b></p> <ul style="list-style-type: none"> <li>• severe diarrhoea*</li> </ul> <p><b>Liver related</b></p> <ul style="list-style-type: none"> <li>• symptoms might include itching, yellow eyes or skin or dark urine (tea-colored), pain or discomfort in the right upper area of the stomach, feeling very tired, decreased appetite, bleeding or bruising more easily than normal.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

\* Less serious diarrhoea is very common with TUKYSA but rarely, severe diarrhoea can occur. Severe diarrhoea can lead to serious consequences such as loss of too much body fluid (dehydration), low blood pressure, kidney problems and death. Tell your doctor right away at the first sign of diarrhoea. Your doctor may prescribe medicines to treat the diarrhoea and/or change your dose of TUKYSA.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Depending on the side effects you have, your doctor may recommend lowering your dose or temporarily stopping your treatment.

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What TUKYSA contains

<b>Active ingredient (main ingredient)</b>	tucatinib
<b>Other ingredients (inactive ingredients)</b>	Copovidone, crospovidone, sodium chloride, potassium chloride, sodium bicarbonate, silicon dioxide, magnesium stearate, microcrystalline cellulose, Opadry II Yellow 85F9272

**Do not take this medicine if you are allergic to any of these ingredients.**

### What TUKYSA looks like

TUKYSA film coated tablets are yellow and debossed with "TUC" on one side and "50" or "150" on the reverse side.

TUKYSA 150 mg Tablets are available in packs of 84 tablets (AUST R 328526)

TUKYSA 50 mg Tablets is available in packs of 88 tablets (AUST R 328525)

### Who distributes TUKYSA

Pfizer Australia Pty Ltd  
Level 17, 151 Clarence Street

Sydney NSW 2000.

Toll Free Number: 1800 675 229.

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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