

TUKYSA[®] FILM-COATED TABLET

Tucatinib (50 mg & 150 mg)

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What TUKYSA is used for

TUKYSA is used for adults who have breast cancer which:

- has a receptor (target) on the cancer cells called human epidermal growth factor receptor 2 (HER2-positive breast cancer)
- has spread beyond the original tumour or to other organs such as the brain or cannot be removed by surgery
- has previously been treated with certain other breast cancer treatments

TUKYSA is taken with two other cancer medicines, trastuzumab and capecitabine. Separate patient information leaflets may be available for these medicines. Ask your doctor to tell you about them.

Ask your doctor if you have any questions about why TUKYSA has been prescribed for you.

TUKYSA should not be used in children under the age of 18 years. The safety of TUKYSA and how effective it is has not been studied in this age group.

How TUKYSA works

TUKYSA contains the active substance tucatinib and it belongs to a group of medicines called protein kinase inhibitors which prevent the growth of some types of cancer cells in the body.

TUKYSA works by blocking the HER2 receptors on cancer cells. HER2 produces signals that can help the cancer to grow, and blocking it may slow or stop cancer cells from growing or may kill them altogether.

Before you use TUKYSA

- When you must not use it

Do not take TUKYSA

- if you are allergic to tucatinib or any of the other ingredients of this medicine

- Before you start to use it

1. Talk to your doctor before taking TUKYSA if you have liver problems. During your treatment, your doctor will run tests to check that your liver is working properly.
2. TUKYSA may cause harm to an unborn baby when taken by a pregnant woman. Your doctor will do a pregnancy test before you start taking TUKYSA. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. The doctor will weigh the potential benefit to you against the risk to the unborn baby.
3. It is not known whether TUKYSA passes into breast milk. If you are breast feeding or planning to breast feed, ask your doctor for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking TUKYSA if you have any questions.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way TUKYSA works or TUKYSA may affect the way they work.

These medicines include some medicines in the following groups:

- St John's wort – a herbal product used to treat depression
- itraconazole, ketoconazole, voriconazole, posaconazole – used to treat fungal infections
- rifampicin – used to treat bacterial infections
- darunavir, saquinavir, tipranavir – used to treat HIV
- phenytoin, carbamazepine – used to treat epilepsy or a painful condition of the face called trigeminal neuralgia or to control serious mood disorder when other medicines do not work
- buspirone – used to treat certain mental health problems
- sirolimus, tacrolimus – used to control your body's immune response after a transplant
- digoxin – used to treat heart problems
- lomitapide, lovastatin – used to treat abnormal cholesterol levels
- alfentanil – used for pain relief
- avanafil, vardenafil – used to treat erectile dysfunction
- darifenacin – used to treat urinary incontinence
- midazolam, triazolam – used to treat seizures, anxiety disorders, panic, agitation, and insomnia
- repaglinide – used to treat type 2 diabetes
- ebastine – an antihistamine used to treat seasonal and perennial allergic rhinitis and rhino-conjunctivitis
- everolimus, ibrutinib – used to treat certain cancers
- naloxegol – used to treat constipation

How to use TUKYSA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

The recommended dose is 300 mg (two 150 mg tablets) by mouth twice a day.

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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.

- When to use it

TUKYSA can be taken with food or between meals.

- Swallow the tablets whole, one after the other.
- Take each dose about 12 hours apart at the same times every day.
- Do not chew or crush the tablet.
- Do not take an additional dose if you vomit after taking TUKYSA but continue with the next scheduled dose.

- How long to use it

TUKYSA is for long-term treatment and you should take it continuously. Do not stop taking TUKYSA without talking to your doctor.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the scheduled time.

- If you use too much (overdose)

Talk to a doctor or pharmacist straight away. If possible, show them the pack.

While you are using TUKYSA

- Things you must do

- TUKYSA can cause severe diarrhoea. Talk to your doctor right away at the first sign of diarrhoea (loose stool) and if your diarrhoea persists with nausea and/or vomiting.
- Depending on the side effects you have, your doctor may recommend lowering your dose or temporarily stopping your treatment.
- Your doctor will also check your liver function during treatment with 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 and have 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 of continuing this medicine and the risk to the unborn baby.
- TUKYSA is not expected to affect your ability to drive or operate machines. However, you are responsible for deciding whether you can drive a motor vehicle or perform other tasks that require increased concentration.

- Things you must not do

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem the same as yours.
- 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.

- Things to be careful of

TUKYSA contains sodium and potassium
This medicine contains 55.3 mg sodium (main component of cooking/table salt) in each 300 mg dose. This is equivalent to 2.75% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 60.6 mg potassium per 300 mg dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Side effects

Like all medicines, this medicine can cause side effects, although not

everybody gets them. The following side effects may occur with this medicine.

Very common (may affect more than 1 in 10 people):

- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- mouth sores, inflammation of the mouth, mouth ulcers
- liver problems, which may cause itching, yellowing of eyes and skin, dark urine and pain or discomfort in the upper right area of the stomach
- rash
- joint pain
- weight loss
- nosebleed

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TUKYSA

- Storage

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

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Product Description

- What it looks like

TUKYSA 50 mg film-coated tablets are round, yellow and debossed with “TUC” on one side and “50” on the reverse side.

TUKYSA 150 mg film-coated tablets are oval shaped, yellow and debossed with “TUC” on one side and “150” on the reverse side.

TUKYSA is supplied in aluminium foil blisters. Each pack contains:

TUKYSA 50 mg film-coated tablets

- 88 or 120 tablets

TUKYSA 150 mg film-coated tablets

- 60 or 84 tablets

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient

The active substance is tucatinib.

Each film-coated tablet contains either 50 mg or 150 mg tucatinib.

- Inactive ingredients

The other ingredients are:

- Tablet core: copovidone (E1208), crospovidone (E1202), sodium chloride, potassium chloride (E508), sodium hydrogen carbonate (E500), silica, colloidal anhydrous (E551), magnesium stearate, microcrystalline cellulose.

- Film-coating: poly (vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), yellow iron oxide (E172).

- MAL number:

TUKYSA 50 mg film-coated tablets:

MAL23086001ACRZ

TUKYSA 150 mg film-coated tablets:

MAL23086002ACRZ

Manufacturer

Corden Pharma GmbH

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Date of revision

10/04/2026

Serial Number:

NPRA (R1) 23/012

PLD-TUKYSA-0426

Product Registration Holder