

Patient leaflet in accordance with the Pharmacists’ Regulations (Preparations) - 1986

This medicine is dispensed with a doctor’s prescription only

Tykerb

Film-coated tablets

Active ingredient:

Each film-coated tablet contains:

lapatinib (as ditosylate monohydrate) 250 mg

Inactive ingredients and allergens: See section 2 under ‘Important information about some of this medicine’s ingredients’, and section 6 ‘Additional information’.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Tykerb is administered in combination with other anti-cancer medicines:

- Tykerb is administered **in combination with capecitabine**, for patients who have had treatment for advanced or metastatic breast cancer before. The previous treatment for metastatic breast cancer must have included anthracyclines, taxanes and trastuzumab.

- Tykerb is administered **in combination with letrozole** for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

Information about these medicines is described in their patient information leaflets. **Ask your doctor** for information about these other medicines.

Tykerb is used to treat certain types of breast cancer (*HER2-overexpressing*) which have spread beyond the original tumour or to other organs (*advanced or metastatic breast cancer*). It may slow or stop cancer cells from growing or may kill them.

Therapeutic group:

Tykerb is a human epidermal growth factor receptor 2 (HER2 receptor) tyrosine kinase inhibitor for the treatment of breast cancer.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient lapatinib or to any of the other ingredients in this medicine, see section 6.

Special warnings about using this medicine

Your doctor will perform tests to check that your heart is working properly before and during treatment with Tykerb.

Tell your doctor if you have any heart problems before treatment with Tykerb.

Before you take Tykerb, your doctor needs to know if you have:

- lung disease
- inflammation of the lung
- any **liver problems**
- any **kidney problems**
- diarrhoea (see section 4)

Your doctor will perform tests to check that your liver is working properly before and during treatment with Tykerb.

Tell your doctor if any of these apply to you.

Serious skin reactions

Serious skin reactions have been seen with use of Tykerb. Symptoms may include skin rash, blisters and skin peeling.

Tell your doctor as soon as possible if you get any of these symptoms.

Tests and follow-up

- Depending on the side effects you experience, your doctor may recommend reducing your dosage or stopping your treatment temporarily.
- Your doctor will also refer you for heart and liver function tests before and during treatment with Tykerb.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

It is especially important to tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines. Some medicines may affect the way Tykerb works or Tykerb may affect how other medicines work. These medicines include some medicines in the following groups:

- hypericum (St. John’s wort) - an herb extract used to treat **depression**.
- erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, rifabutin, rifampicin, telithromycin – medicines for treatment of **infections**.
- cyclosporine – a medicine **to suppress the immune system** for example after organ transplantation.
- ritonavir, saquinavir – medicines for the treatment of **HIV**.
- phenytoin, carbamazepine – medicines for the treatment of **seizures** (epilepsy).
- cisapride – a medicine for the treatment of certain **digestive system** problems.
- pimozide – a medicine for the treatment of certain **mental health** problems.
- quinidine, digoxin – medicines for the treatment of certain **heart problems**.
- repaglinide – a medicine for the treatment of **diabetes**.
- verapamil – a medicine for the treatment of **high blood pressure** or **heart problems** (angina).
- nefazodone – a medicine for the treatment of **depression**.
- topotecan, paclitaxel, irinotecan, docetaxel – medicines for the treatment of certain types of **cancer**.
- rosuvastatin – a medicine for the treatment of **high cholesterol**.
- medicines that decrease stomach acidity - used to treat **stomach ulcers** or **indigestion**.

Your doctor will review the list of medicines you are currently taking to make sure you are not taking a medicine that cannot be used in combination with Tykerb. Your doctor will tell you whether an alternative is available.

Using this medicine and food

Do not drink grapefruit juice while you are being treated with Tykerb. Grapefruit juice can affect the activity of the medicine.

Take Tykerb at least one hour before or at least one hour after food. Take Tykerb at the same time in relation to food each day. For example, you could always take the tablets one hour before breakfast.

Pregnancy, breast-feeding and fertility

The effect of Tykerb during pregnancy is not known. Do not take Tykerb if you are pregnant unless your doctor specifically recommends it.

- **If you are pregnant** or planning to become pregnant, **tell your doctor**.
- **Use a reliable method of contraception** to avoid becoming pregnant while you are taking Tykerb and for at least five days after the last dose.
- **If you become pregnant** during treatment with Tykerb, **tell your doctor**.

It is not known whether Tykerb passes into breast milk. Do not breast-feed while taking Tykerb and for at least five days after the last dose.

- **If you are breast-feeding** or planning to breast-feed, **tell your doctor**.

Consult your doctor or pharmacist before starting treatment with Tykerb if you are unsure.

Driving and using machines

You are responsible for deciding if you are able to drive a motor vehicle or perform other tasks that require a high level of concentration. Because of the possible side effects of Tykerb, your ability to drive or operate machines could be affected. These effects are described in section 4, ‘Side effects’.

Important information about some of this medicine’s ingredients

This medicine contains sodium. The amount of sodium in the tablet is less than 23 mg sodium, that is to say essentially “sodium free”.

3. How to use this medicine?

Always use this medicine according to your doctor’s instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine, depending on the type of breast cancer the treatment was prescribed for.

The recommended dosage is usually:

If Tykerb is given **in combination with capecitabine**, the usual dosage is **5 Tykerb tablets a day**, as a single dose.

If Tykerb is given **in combination with letrozole**, the usual dosage is **6 Tykerb tablets a day**, as a single dose.

Take the prescribed dose every day for as long as your doctor tells you to.

Your doctor will advise you about the dosage of your other anti-cancer medicines, and how to take them.

Do not exceed the recommended dose.

Method of administration

Swallow the tablets whole with water, one after the other, at the same time each day. See also section 2 ‘Using this medicine and food’.

Crushing/splitting/chewing: There is no information about crushing/splitting/chewing.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Tykerb may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

A severe allergic reaction is a rare side effect (may affect 1-10 in 10,000 users) and may develop rapidly.

Symptoms may include:

- skin rash (including bumpy, itchy rash).
- unusual wheezing or difficulty breathing.
- swollen eyelids, lips or tongue.
- pains in muscles or joints.
- collapse or blackout.

Contact your doctor immediately if you have any of these symptoms. Don’t take any more tablets.

Very common side effects (effects that appear in more than one in ten users):

- diarrhoea (which may cause dehydration and lead to more severe complications)
- **Contact your doctor immediately at the first sign of diarrhoea (loose stool), as it is important to treat diarrhoea right away. Also tell your doctor immediately if your diarrhoea worsens. Additional tips for reducing the risk of diarrhoea appear at the end of section 4.**

- rash, dry skin ,itching.

Tell your doctor if you have a skin rash. *Additional tips for reducing the risk of skin rash appear at the end of section 4.*

Additional very common side effects (effects that appear in more than one in ten users):

- loss of appetite
- nausea
- vomiting
- tiredness and feeling weak
- Indigestion
- constipation
- mouth sores/ulcers
- stomach pain
- trouble sleeping
- back pain
- pain in hands and feet
- joint pain
- a skin reaction on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)
- cough, shortness of breath
- headache
- nose bleed
- hot flushes
- unusual hair loss or thinning

Tell your doctor if any of these side effects becomes severe or troublesome.

Common side effects (effects that appear in 1-10 in 100 users):

- an effect on how your heart functions.

In most cases, the effect on your heart will not have any symptoms. If you do experience symptoms associated with this side effect, they will evidently include an irregular heartbeat and shortness of breath.

- liver problems, which may cause itching, yellow eyes or skin (*jaundice*), or dark urine or pain or discomfort in the right upper area of the stomach.
- results of blood tests that indicate changes in liver function (usually mild and temporary).
- nail disorders, such as a tender infection and swelling of the cuticles (the skin at the base of the nail).
- skin fissures (deep cracks on the skin or chapped skin).

Contact your doctor if any of these symptoms appear.

Uncommon side effects (effects that appear in 1-10 in 1,000 users):

- treatment-induced lung inflammation, which may cause shortness of breath or cough.

Contact your doctor immediately if you sense either of these symptoms.

Rare side effects (effects that appear in 1-10 in 10,000 users):

- severe allergic reactions (*see the beginning of section 4*).

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- irregular heartbeat (change in the electrical activity of the heart)
- severe skin reaction that might include: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever or any combination of these
- pulmonary arterial hypertension (increased blood pressure in the arteries (blood vessels) of the lungs)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reducing the risk of diarrhoea and skin rash

Tykerb can cause severe diarrhoea

If you suffer from diarrhoea while taking Tykerb:

- drink plenty of fluids (8 to 10 glasses a day), such as water, sports drinks or other clear liquids.
- eat low-fat, high-protein foods instead of fatty or spicy foods.
- eat cooked vegetables instead of raw vegetables, and remove the skin from fruits before eating.
- avoid milk and milk products (including ice cream).
- avoid herbal supplements (some may cause diarrhoea).

Contact your doctor if your diarrhoea continues.

Tykerb can cause skin rash

Your doctor will check your skin before and during treatment.

Treatment for sensitive skin:

- use a soap-free cleanser.
- use fragrance free, hypoallergenic beauty products.
- use sunscreen (Sun Protection Factor [SPF] 30 or higher).

Tell your doctor if you have a skin rash.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Use within 30 days of first opening of the bottle.

Do not store above 30°C.

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

6. Additional information

• **In addition to the active ingredient, this medicine also contains:**

Microcrystalline cellulose, povidone (K30), sodium starch glycolate (TypeA), hypromellose, magnesium stearate, titanium dioxide (E171), macrogol 400, polysorbate 80, iron oxide yellow (E172), iron oxide red (E172).

• **What the medicine looks like and contents of the pack:**

Tykerb film-coated tablets are oval, biconvex, yellow film-coated, with ‘GS XJG’ marked on one side.

Tykerb comes in a bottle containing 70 film-coated tablets.

• **Registration holder and importer’s name and address:**

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

- Registration number of the medicine in the Ministry of Health’s National Drug Registry: 139-23-31609.

Revised in March 2022 according to MOH guidelines.