

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed according to a physician's prescription only

Tykerb® Film-coated tablets

The active ingredient in Tykerb is lapatinib. Each film-coated tablet contains: lapatinib (as ditosylate monohydrate) 250 mg.

The list of additional ingredients is detailed in Section 6 “Additional information”. See also section 2 “Important information about some of the ingredients of the medicine”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for the treatment of 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

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). The medicine may slow or stop cancer cells from growing, or may kill them.

Tykerb is given in combination with other anti-cancer medicines.

Tykerb is given in **combination with capecitabine**, for patients who have had treatment for advanced or metastatic breast cancer before. This previous treatment for the metastatic breast cancer must have included an anthracycline, a taxane and trastuzumab.

Tykerb is given in **combination with letrozole**, for postmenopausal women with hormone receptor positive metastatic breast cancer that overexpress the HER2 receptor and who are candidates for hormonal therapy. Information about these medicines can be found in their patient information leaflets. **Ask your physician** for information about these other medicines.

Therapeutic group

Tykerb is a Tyrosine Kinase Inhibitor for treatment of breast cancer.

2. BEFORE USING THE MEDICINE

ⓘ Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine as listed in section 6.

Special warnings regarding the use of the medicine:

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

ⓘBefore treatment with Tykerb, tell your physician if you have any heart problems. In addition, before you take Tykerb, your physician needs to know if you have:

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

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

Tell your physician if any of these apply to you.

ⓘSerious skin reactions

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

Refer to your physician as soon as possible if you experience any of these symptoms.

ⓘTests and follow-up

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

ⓘDrug interactions:

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. It is particularly important to inform the physician or the 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) – a herbal extract for the treatment of **depression**.

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

Your physician will review the medicines you are currently taking to make sure you are not taking something that can’t be taken in combination with Tykerb. Your physician will advise you whether an alternative is available.

ⓘUse of the medicine and food

Don’t drink grapefruit juice while you are being treated with Tykerb. It can affect the way the medicine works.

Take Tykerb either 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 your tablet one hour before breakfast.

ⓘPregnancy, breast-feeding and fertility

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

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

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 physician**.

Ask your physician or pharmacist for advice before taking Tykerb if you are unsure.

ⓘDriving and using machines

You are responsible to decide if you are able to drive a motor vehicle or perform other tasks that require increased 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 the ingredients of the medicine

This medicine contains sodium. The amount of sodium is less than 23 mg sodium per tablet, i.e., essentially “sodium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.

Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment will be determined only by the physician depending on the type of breast cancer being treated.

The usual dose is generally:

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

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

Take the prescribed dose daily, for as long as your physician instructs you to do so.

Your physician 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.

Also see section 2 “Use of the medicine and food”.

Crushing/halving/chewing: there is no information regarding crushing/splitting/chewing.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

Do not take a double dose to make up for a missed dose. Take the next dose at the scheduled time and consult the doctor.

Persist with the treatment as recommended by the physician.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician.

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

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tykerb may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

Symptoms may include:

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

Refer to your physician immediately if you have any of these symptoms. Do not take any more tablets.

Very common side effects (effects that occur in more than 1 user in 10):

- diarrhoea (may cause dehydration and lead to more severe complications)

Refer to your physician immediately at the first sign of diarrhoea (loose stool), as it is important that this is treated right away. Also tell your physician immediately if your diarrhoea worsens. *Additional advice on reducing the risk of diarrhoea appears at the end of section 4.*

- rash, dry skin, itching

Refer to your physician if you get a skin rash. *Additional advice on reducing the risk of skin rash appears at the end of section 4.*

Other very common side effects (effects that occur in more than 1 user in 10):

- loss of appetite
- nausea
- vomiting
- tiredness, feeling weak
- indigestion
- constipation
- sore mouth/mouth ulcers
- stomach pain
- trouble sleeping
- back pain
- pain in palms of the hands and feet
- joint pain

- a skin reaction on the palms of the hands or feet (including tingling, numbness, pain, swelling or reddening)
- cough, shortness of breath
- headache
- nose bleed
- hot flush
- unusual hair loss or thinning

Tell your physician if these effects become serious or problematic.

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

- an effect on how your heart works.

In most cases, the effect on your heart will not have any symptoms. If you do experience symptoms associated with this side effect, these are likely to 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.
- blood tests results that show changes in liver function (usually mild and temporary changes).
- nail-related disorders, for example, an infection causing tenderness and swelling of the cuticles (the skin at the base of the nail).

Refer to your physician if you get any of these symptoms.

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

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

Refer to your physician immediately if you have either of these symptoms.

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

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

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- irregular heart rate (change in the electrical activity of the heart)
- serious skin reaction that can include: rash, red skin, blisters on 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 a side effect occurs, if any of the side effects gets worse, or when you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

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 cause diarrhoea).

Refer to your physician if your diarrhoea continues.

Tykerb can cause skin rash

Your physician will check your skin before and during treatment.

To care 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 physician if you get a skin rash.

Side effects can be reported to the Ministry of Health by clicking the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

Do not use the medicine after the expiry date (exp. date) appearing on the package and the bottle. The expiry date refers to the last day of that month.

Storage conditions:

After first opening of the bottle, can be used within 30 days.

Do not store above 30°C.

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

6. ADDITIONAL INFORMATION

• In addition to the active ingredient the medicine also contains:

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

• What does the medicine looks like and what is the content of the package:

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

Tykerb is supplied in a bottle of 70 film-coated tablets.

- Registration Holder and Importer and its address:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

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

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