

TYKERB®

250 mg film coated tablets

Lapatinib Ditosilate

NZ Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take TYKERB.

This leaflet answers some common questions about TYKERB (lapatinib). It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking TYKERB against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is TYKERB used for?

TYKERB contains the active ingredient lapatinib, which belongs to a group of medicines called protein kinase inhibitors.

TYKERB is used to treat certain types of breast cancer. Breast cancer is caused by cells that divide abnormally in the breast. These cells may reach other tissues of the body at a later stage in a process called metastasis. TYKERB may slow or stop cancer cells from growing, or may kill them.

TYKERB is prescribed for the treatment of patients with advanced or metastatic breast cancer who have tumours that produce large amounts of a protein called human epidermal growth factor receptor-2 (HER2, also known as ErbB2).

While taking TYKERB for this condition, you will also take another medicine, either:

- Capecitabine tablets (Xeloda®) **or**
- Paclitaxel (Paclitaxel Ebewe®, Abraxane®, or Anzatax®) which is given as an infusion in a hospital or clinic.

For tumours which are hormone-sensitive, TYKERB may be given with an aromatase inhibitor tablet.

Information about these other medicines is described in separate Consumer Medicine Information.

Please read the information for the other medicines that you have been prescribed with TYKERB.

Your doctor may have prescribed TYKERB for another reason.

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

TYKERB is not addictive.

Before you take TYKERB

When you must not take it

Do not take TYKERB if you have an allergy to

- lapatinib (active ingredient), or
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before you take TYKERB, your doctor needs to know if you have or have had any of the following medical conditions:

- heart disorders, such as an irregular heartbeat, heart failure
- lung disorders or problems breathing, including pain while breathing
- liver disorders.

Check with your doctor if you think any of these may apply to you.

You may need extra tests to check that your heart and liver are working properly. Your doctor may decide to adjust your dose or stop treatment based on the results of these tests.

Taking other medicines with TYKERB

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines including any medicines you bought without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and TYKERB may interfere with each other. These include:

- Some medicines used to treat infections such as:
 - ketoconazole
 - itraconazole
 - posaconazole
 - voriconazole
 - erythromycin
 - rifabutin
 - rifampicin
 - telithromycin
- Some medicines used to treat HIV such as:
 - ritonavir
 - saquinavir.

- Cisapride – a medicine used to treat some gastrointestinal conditions
- Esomeprazole or other medicines used to decrease stomach acidity, stomach ulcers or indigestion
- Medicines used for sedation before surgery (anaesthesia), such as midazolam
- Some medicines used to treat heart problems such as quinidine, digoxin.
- Verapamil which is used to treat high blood pressure or angina
- Rosuvastatin – a medicine that reduces cholesterol
- Repaglinide – a diabetic medicine
- Phenytoin and carbamazepine - medicines used to treat seizures (epilepsy)
- Pimozide – a medicine used to treat mental health problems
- Some antidepressant medicines such as nefazodone and the herbal extract St John's Wort (*Hypericum perforatum*)
- Cyclosporine (used to prevent the rejection of transplanted organ)
- Some anticancer agents such as:
 - topotecan
 - paclitaxel
 - irinotecan
 - docetaxel.

Tell your doctor if you are taking any of these medicines.

Pregnancy

If you are pregnant, think you could be pregnant, or are planning to have a baby, ask your doctor or healthcare provider for advice before taking TYKERB.

If you become pregnant or think you are pregnant, tell your doctor or healthcare provider right away.

TYKERB may harm your unborn baby.

You should avoid becoming pregnant while you're taking TYKERB.

Use a reliable method of birth control (contraception) during treatment and for at least 5 days after stopping TYKERB.

Ask your doctor about effective contraception options

Your doctor may recommend that you do not take TYKERB while you are pregnant.

Breast feeding

Do not breast-feed while taking TYKERB and for 5 days after the last dose as it may harm your baby.

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

Your doctor will discuss with you the risks of taking TYKERB during breast-feeding.

Taking TYKERB with food and drink

TYKERB is affected by food intake and must be taken on an empty stomach, at least 1 hour before or 1 hour after eating.

You should not drink grapefruit juice or eat grapefruit during your treatment with TYKERB. It may make this medicine less effective and possibly increase the chance of side effects.

Driving and using machines

TYKERB can cause tiredness and may make you unfit to drive. Do not drive or operate machinery unless you're feeling well and until you know how TYKERB affects you.

How to take TYKERB?

Follow all directions given to you by your doctor, pharmacist or nurse carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor, pharmacist, or nurse for help.

Your doctor will tell you exactly how many TYKERB tablets that you should take.

Depending on your response to TYKERB or if you have heart, lung or liver problems, or experience serious episodes of diarrhoea or skin reactions during treatment with TYKERB, your doctor may prescribe a lower dose or temporarily stop treatment..

How much to take

Your doctor will tell you the dose of capecitabine, paclitaxel or aromatase inhibitor that you should take and when you should take it.

If you are aged 65 years or above you can use TYKERB at the same dose as for other adults.

In combination with capecitabine:

The usual dose is five (5) TYKERB tablets taken once a day (a total dose of 1250 mg).

In combination with paclitaxel:

The usual dose is six (6) TYKERB tablets taken once a day (a total dose of 1500 mg).

In combination with an aromatase inhibitor:

The usual dose is six (6) TYKERB tablets taken once a day (a total dose of 1500 mg).

Your doctor may decide that you should take a lower dose if you get side effects.

Do not take any more TYKERB than your doctor has recommended.

How to take it

TYKERB tablets should be swallowed whole with a full glass of water, one after the other, at about the same time each day.

TYKERB film-coated tablets should not be chewed, crushed or split prior to swallowing.

If you have to take another medicine to treat your breast cancer in addition to Tykerb, follow your doctor's instructions on how to take that medicine.

When to take it

Take TYKERB on an empty stomach, once a day, at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If taking TYKERB BEFORE something to eat or drink, take the tablets and then wait at least one (1) hour before eating or having something to drink.

If Taking TYKERB AFTER eating a meal or snack, wait at least 1 hour before taking TYKERB.

If you are being treated with a combination of TYKERB and:

- **paclitaxel**
your doctor will advise you about the dose of paclitaxel, and how often you will receive it.
- **capecitabine**
your doctor will advise you about the dose of capecitabine, when to take it and how often.
- **an aromatase inhibitor**
your doctor will advise you about the dose of the aromatase inhibitor, when to take it and how often.

How long to take it for

Keep taking TYKERB for as long as your doctor tells you. Don't stop unless your doctor advises you to.

Stopping your treatment with TYKERB is likely to cause your condition to become worse.

This is a long-term treatment that may continue for months or years. Your doctor will regularly monitor

your condition to check that the treatment is having the desired effect.

If you have questions about how long to take TYKERB, talk to your doctor or healthcare provider.

If you forget to take TYKERB

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose at the usual time. Otherwise, take it as soon as you remember, and then go back to taking your next dose at the scheduled time.

Don't take a double dose to make up for a missed dose.

This may increase your risk of having a side effect.

If you have trouble remembering to take your medicine, ask your doctor, nurse or pharmacist for some hints.

If you take too much (overdose)

If you have taken too much TYKERB, or if somebody else accidentally takes your medicine, immediately telephone your doctor or the National Poisons Centre (0800 POISON or 0800 764 766) for advice, or go to the nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

Take your medications with you.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using TYKERB

Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

If you have any questions on the use of this medication, ask your doctor or nurse.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TYKERB.

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (from time to time to make sure the medicine is working and to prevent unwanted side effects. Your heart, lung and liver function will be regularly checked before and during treatment with Tykerb.

If you are a woman that could become pregnant, you must use an effective contraceptive to prevent pregnancy during treatment with TYKERB and for 5 days after the last dose of TYKERB.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TYKERB.

Things you must not do

Do NOT take TYKERB with food. You must take it on an empty stomach.

TYKERB is affected by food intake (See How to Take TYKERB)

Do NOT drink grapefruit juice or eat grapefruit while you are being treated with TYKERB.

Do NOT give this medicine to anyone else, even if their symptoms seem similar to yours.

Do NOT use TYKERB to treat any other complaints unless your doctor says to.

Do NOT stop taking your medicine or lower the dosage without checking with your doctor.

Do not dispose of medicines in wastewater or household rubbish.

This will help to protect the environment.

Things to be careful of

Severe skin reactions have been seen with TYKERB. Symptoms may include:

- skin rash
- blisters
- skin peeling.

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

As severe skin reactions can be life threatening, your doctor may tell you to stop TYKERB.

Possible side effects

As with all medicines, patients treated with Tykerb alone or in combination with capecitabine, paclitaxel, or an aromatase inhibitor may experience side effects, although not everybody gets them.

Do not be alarmed by these possible side effects.

You may not experience any of them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Tykerb, even if the problem is not listed below.

These side effects have occurred with Tykerb alone, or in combination with

capecitabine, paclitaxel or letrozole (an aromatase inhibitor).

Serious side effects

STOP taking Tykerb and seek medical help immediately if you experience any of the following side effects.

Very common serious side effects

These may affect more than 1 in 10 people:

- Fever, sore throat, frequent infections as signs of low level of white blood cells (leukopenia)
- Pale skin, weakness, frequent infections with fever, chills and sore throat as signs of low level of red blood cells (anaemia).

Common serious side effects

These may affect up to 1 in 10 people:

- Irregular heartbeat and shortness of breath (decreased left ventricular ejection fraction).

Uncommon serious side effects

These may affect up to 1 in 100 people:

- Itching, yellow eyes or skin (jaundice), dark urine or pain or discomfort in the right upper area of the stomach (hepatotoxicity or hyperbilirubinemia)
- Cough or shortness of breath (interstitial lung disease and/or pneumonitis).

Rare serious side effects

These may affect up to 1 in 1000 people:

- Skin rash (including itchy, bumpy rash), skin reddening, hives, unusual wheezing or coughing or difficulty breathing, swollen eyelids, lips, face or tongue, blue discoloration of the lips, tongue, or skin, pain in muscles or joints, light-headedness, dizziness, loss of consciousness (passing out), hypotension (signs of severe allergic reactions).

Frequency unknown serious side effects

The frequency of these side effects is not known (events from spontaneous reports):

- Irregular heart-beat (ventricular arrhythmia/Torsade de Pointes)
- Change in the electrical activity of the heart (QT interval in the electrocardiogram prolonged)
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever or any combination of these (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Other possible side effects

Other side effects include those listed below. If these side effects are severe, please tell your doctor, pharmacist or healthcare provider immediately.

Very common

These may affect more than 1 in 10 people:

- Diarrhoea (can be life-threatening if severe); report any serious change in bowel patterns, such as loose stool immediately.
- A skin reaction or pain on the palms of the hands or soles of the feet, including tingling, numbness, pain, swelling or reddening (palmar-plantar erythrodysesthesia or hand-foot syndrome)
- Muscle pain
- Numbness, tingling or weakness of the arms and legs
- Loss of appetite (anorexia)
- Indigestion or stomach pain (dyspepsia)
- Feeling or being sick (nausea or vomiting)
- Constipation
- Tiredness (fatigue)
- Unusual hair loss or thinning (alopecia)
- Nose bleed (epistaxis)
- Sore mouth or mouth ulcers (mucosal inflammation)
- Trouble sleeping (insomnia)

- Back pain
- Pain in extremity
- Dry skin
- Rash.

Common

These may affect up to 1 in 10 people:

- Headache
- Nail disorders - such as a tender infection and swelling of the bottom part of the nail (cuticles).
- Deep cracks on the skin or chapped skin (skin fissures)

If you notice any side effects not listed, please inform your doctor or healthcare provider.

After using TYKERB

Storage

Keep your tablets in the original pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store TYKERB or any other medicine in the bathroom, near a sink, on a window sill, or in the car.

Heat and dampness can destroy some medicines

Keep TYKERB where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Dispose of medicines safely. Ask your pharmacist how to dispose of tablets you do not need.

If you have any unwanted tablets, don't put them in wastewater or household rubbish. Do not throw

TYKERB in the general household rubbish or flush it down the toilet.

It may end up in landfill or enter waterways affecting the environment or marine life.

Do not keep old medicines because you think you may need them in the future.

Keeping any unwanted or expired medications runs the risk of unintentional poisonings.

Product description

What TYKERB looks like

TYKERB tablets are oval, biconvex, yellow film-coated, and with GS XJG debossed on one side.

TYKERB is available in bottle packs containing 70 tablets.

Ingredients

TYKERB contains the active ingredient lapatinib ditosilate monohydrate. Each film-coated tablet contains 250 mg of lapatinib. TYKERB also contains:

- Cellulose - microcrystalline (E460)
- Povidone (E1201)
- Sodium starch glycolate
- Magnesium stearate (E572)
- Hypromellose (E464)
- Titanium dioxide (E171)
- Macrogol (E1521)
- Polysorbate (E433)
- Iron oxide yellow (E172)
- Iron Oxide Red (E172).

This medicine does not contain lactose, sucrose, tartrazine, or azo dyes.

Sponsor

TYKERB is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand

Telephone 0800 354 335

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