

TYKERB[®] 250 mg film coated tablets

Lapatinib Ditosylate

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.

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 is used to treat certain types of breast cancer. It 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 containing capecitabine (Xeloda[®]). Information about capecitabine is

described in the capecitabine Consumer Medicine Information leaflet.

TYKERB is prescribed for the treatment of patients with hormone sensitive metastatic breast cancer where the tumours have receptors for the hormones oestrogen and/or progesterone, and 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 an aromatase inhibitor. Ensure you read the Consumer Medicine Information leaflet for the aromatase inhibitor.

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

Do not take if:

You must not take TYKERB if:

- you have ever had a severe allergic (hypersensitive) reaction to TYKERB (lapatinib). Check with your doctor if you think this may apply to you.
- you have ever had an allergic reaction to any of the ingredients listed toward the end of this leaflet. (See "Ingredients")

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

Before you take TYKERB your doctor needs to know:

- If you have any heart problems.
- If you have any lung problems or problems breathing.
- If you have any liver problems.

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.

Other medicines and 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. This includes herbal medicines.

Some medicines may affect the way TYKERB works or TYKERB may affect how other medicines work. These include:

- erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, rifabutin, rifampicin, telithromycin (used to treat infections)
- ritonavir, saquinavir (used to treat HIV)
- cisapride (used to treat digestive system problems)

- drugs that decrease stomach acidity (used to treat stomach ulcers or indigestion)
- quinidine, digoxin (used to treat heart problems)
- verapamil (used to treat high blood pressure or angina)
- rosuvastatin (used to treat high cholesterol)
- repaglinide (used to treat diabetes)
- phenytoin, carbamazepine (used to treat seizures)
- pimozide (used to treat mental health problems)
- nefazodone (used to treat depression)
- St John's Wort (a herb extract used to treat depression)
- cyclosporine (used to suppress the immune system for example after organ transplantations)
- topotecan, paclitaxel (used to treat cancer)

Tell your doctor if you are taking any of these.

Taking TYKERB with food and drink

TYKERB is affected by food intake (See *How to Take TYKERB*). You should not drink grapefruit juice while you are being treated with TYKERB as this may increase the chance of side effects.

Pregnancy and breast-feeding

Use a reliable method of contraception to avoid becoming pregnant while you're taking TYKERB.

If you are pregnant or think you could be, talk to your doctor about the risks and benefits of taking TYKERB. Your doctor may recommend that you don't take TYKERB while you are pregnant.

Breast-feeding is not recommended during treatment with TYKERB. Ask your doctor for advice.

Driving and using machines

TYKERB can cause tiredness and may make you unfit to drive. Don't drive or operate machinery unless you're feeling well.

How do I take TYKERB?

Always take TYKERB exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take

In combination with capecitabine: The usual dose is 5 TYKERB tablets (a total dose of 1250 mg) taken once a day.

In combination with an aromatase inhibitor: The usual dose is 6 TYKERB tablets (a total dose of 1500 mg) taken once a day.

How to take it

Swallow the tablets whole with water, one after the other, at about the same time each day.

It is important that you take TYKERB either at least one hour before or at least one hour after food.

If you are being treated with a combination of TYKERB and capecitabine, your doctor will advise you about the dose of capecitabine, when to take it and how often.

If you are being treated with a combination of TYKERB and an aromatase inhibitor, your doctor will advise you about the dose of the aromatase inhibitor, when to take it and how often.

Depending on your response to treatment, your doctor may recommend lowering your dose of TYKERB or temporarily stopping it.

If you forget to take TYKERB

Don't take a double dose to make up for a missed dose. Take the next dose at the scheduled time.

How long to take it for

Take TYKERB for as long as your doctor recommends. Don't stop unless your doctor advises you to.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia call 131126. In New Zealand call 0800 POISON or 0800 764 766) for advice, if you think you or anyone else may have taken too much TYKERB, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

While you are taking TYKERB

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

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.

What are the side effects?

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.

Like all medicines, TYKERB can cause side effects, although not everybody gets them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

These side effects have occurred with TYKERB in combination with capecitabine or letrozole.

Severe allergic reaction

This rare side effect may affect up to 1 in 1000 people and 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.

Tell your doctor immediately if you get any of these symptoms. Don't take any more tablets.

Very common side effects

These may affect more than 1 in 10 people:

- diarrhoea (which can be severe). Contact your doctor if you are affected, as it is important that this is treated to avoid dehydration.
- loss of appetite
- indigestion or stomach pain
- feeling or being sick (nausea or vomiting)
- constipation
- tiredness
- unusual hair loss or thinning
- nose bleed
- sore mouth or mouth ulcers
- trouble sleeping (insomnia)
- back pain
- rash or dry skin
- a skin reaction or pain on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening).

Common side effects

These may affect up to 1 in 10 people:

- an effect on how your heart works – this may cause an irregular heartbeat and shortness of breath
- liver problems – this may cause itching, yellow eyes or skin (jaundice), dark urine or pain or discomfort in the right upper area of the stomach
- headache
- nail disorders – such as a tender infection and swelling of the cuticles.

Uncommon side effects

These may affect up to 1 in 100 people:

- swelling of the lungs – this may cause coughing or shortness of breath.

Rare side effects

These may affect up to 1 in 1,000 people:

- severe allergic reactions (See the beginning of this section).

If you get side effects

Tell your doctor or pharmacist if any of the side effects listed become severe or troublesome, or if you notice any side effects not listed in this leaflet.

How do I store TYKERB?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Do not store above 30°C.

Do not leave in a car, on a window sill or in a bathroom.

Do not use TYKERB after the expiry date which is stated on the carton.

Keep TYKERB in its blister pack until it's time to take it.

Disposal

If you have any unwanted tablets don't put them in wastewater or household rubbish. Ask your

pharmacist how to dispose of tablets you don't need. This will help to protect the environment.

Product description

What TYKERB looks like

TYKERB is presented in packs of 40, 70, 84 and 168*tablets. *not all pack sizes may be available.

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

Ingredients

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

TYKERB also contains Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Magnesium Stearate, Hypromellose, Titanium Dioxide, Macrogol/PEG400, Polysorbate, Iron Oxide Yellow and Iron Oxide Red.

Sponsor

TYKERB is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia, Victoria, 3155
Australia.

TYKERB is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
AMP Centre
Cnr Albert & Customs Streets
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information:

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist

is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

This leaflet was prepared on 27 April 2010.

The information provided applies only to: TYKERB.

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TYKERB®:
250mg – AUST R 132305

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