NOVARTIS

TYKERB® (lapatinib)

250 mg tablet

Patient Information Leaflet

Document status: Final

Approval date: 14 September 2018

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TYKERB® Tablets

Lapatinib 250 mg

Read all of this leaflet carefully before you start taking TYKERB.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- TYKERB has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT TYKERB CONTAINS:

The active substance is lapatinib ditosylate.

Each film-coated tablet contains lapatinib ditosylate monohydrate equivalent to 250 mg lapatinib.

The other ingredients are microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide, macrogol/PEG 400, polysorbate 80, iron oxide yellow, and iron oxide red.

WHAT TYKERB IS USED FOR:

TYKERB is a medicine that may inhibit cancer cells from growing. It is used to treat certain types of advanced breast cancer and it is given in combination with other medicines like capecitabine, paclitaxel or an aromatase inhibitor e.g. letrozole.

Information about capecitabine, paclitaxel and letrozole is described in separate patient information leaflets.

BEFORE YOU TAKE TYKERB:

Do not take TYKERB:

- If you are have had a severe allergic (hypersensitive) reaction to lapatinib ditosylate or any other ingredient in TYKERB (see **WHAT TYKERB CONTAINS**).
- If you have moderate or severe liver disease

Take special care with TYKERB:

Before you start taking TYKERB, tell your doctor:

- if you have any problems with your heart
- if you have any liver problems
- if you have lung problems or problems breathing
- if you have diarrhoea, or any condition that could lead to electrolyte disturbances, such as eating disorders, vomiting, and dehydration
- if you are pregnant or plan to become pregnant
- if you are breastfeeding.

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.

Severe skin reactions

- Severe skin reactions have been seen with TYKERB. Symptoms may include skin rash, blisters and 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.

TYKERB can cause severe diarrhoea. **Contact your doctor immediately** if you are affected, as it is important that the diarrhoea is treated to avoid dehydration.

Taking TYKERB with food and drink:

TYKERB should be taken at least one hour before or at least one hour after food. You should not drink grapefruit juice while you are being treated with TYKERB as this may increase the chance of side effects.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking TYKERB.
You should avoid becoming pregnant while taking TYKERB. You should use a reliable method of contraception (a way to prevent you from becoming pregnant). If you become pregnant during treatment, tell your doctor immediately.
If you are taking TYKERB, you should not breastfeed your baby.

Driving and using machinery:

Do not drive or operate machinery unless you are feeling well.

Taking other medicines with TYKERB:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicine). There are certain groups of medicines that interact with TYKERB and you may not be able to take them while receiving TYKERB. These medications include some medicines within the following groups:

- medicines used to treat infections (antibiotics and anti-fungals e.g. erythromycin, ketoconazole, itraconazole, voriconazole, rifabutin, rifampicin, teliththromycin))
- HIV (AIDS) treatment (e.g. ritonavir, saquinavir)
- medicines used to treat seizures e.g. phenytoin, carbamazepine
- medicines used to treat certain heart disorders (e.g. quinidine, digoxin) and high blood pressure (e.g. verapamil)
- medicines used to treat cholesterol (e.g. rosuvastatin)
- medicines used to treat depression (e.g. nefazodone and mental health problems (e.g. pimozide)
- medicines used to treat digestive system disorders (e.g. cisapride) and medicines used to treat stomach ulcers or indigestion
- herbal supplements (e.g. St John's Wort, a herb extract to treat depression).
- medicines used to suppress the immune system e.g. after organ transplantations (e.g. cyclosporine)
- medicines used to treat cancer (e.g. topotecan, paclitaxel, irinotecan, docetaxel).

Your doctor will review the medicines you are currently taking to make sure you are not taking something that cannot be taken with TYKERB. If you require any of these medications and a suitable substitute is not available, please discuss this with your doctor.

Because TYKERB is given with other cancer medications e.g. capecitabine, **paclitaxel or letrozole**, you should also discuss with your doctor any medicines that should be avoided when taking capecitabine, paclitaxel or letrozole.

HOW TO 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.

TYKERB should be taken at least one hour before or at least one hour after food.

Your doctor will advise you on the correct dose of TYKERB to be taken depending on the type of breast cancer you have.

TYKERB is given in combination with capecitabine, paclitaxel or letrozole depending on the type of breast cancer you have.

Your doctor will advise you about the correct dose of these other medicines you should receive and when and how often you should take any of the other medicines listed above.

Your doctor will also carry out blood tests to check your liver function and your heart function before and during treatment with TYKERB.

If you forget to take TYKERB:

Do not take a double dose to make up for a forgotten dose on a given day; simply resume your dosing with the next scheduled dose the following day.

If you have any further questions on the use of TYKERB, ask your doctor or pharmacist.

Once you have started taking TYKERB:

Do not stop taking TYKERB until your doctor advises you to do so.

If you have any problems/questions regarding the use of TYKERB, please consult with your doctor.

POSSIBLE SIDE EFFECTS:

Not all side effects reported for TYKERB are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking

TYKERB, please consult your doctor, pharmacist or other healthcare professional for advice.

TYKERB can cause side effects.

Because TYKERB is given with other cancer medicines, you may also get side effects associated with these other cancer medicines.

The following side effects have been reported to be associated with TYKERB when given in combination with capecitabine:

Severe Allergic Reaction:

This side effect 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.

Tell your doctor immediately if you get any of these symptoms. Do not take any more tablets.

Frequent side effects:

- diarrhoea (which may be severe). **Contact your doctor immediately** at the first sign of diarrhoea (loose stool), as it is important that this is treated right away
- loss of appetite (anorexia)
- feeling sick (nausea)
- being sick/throwing up (vomiting)
- rash
- tiredness.

- irregular heartbeat. shortness of breath due to a decrease in the amount of blood pumped by your heart

The following additional side effects have been reported in patients taking TYKERB in combination with capecitabine, paclitaxel or letrozole:

- low levels of white blood cells and red blood cells
- muscle pain
- numbness, tingling or weakness of the arms or legs
- indigestion
- constipation
- unusual hair loss or thinning
- nose bleed
- sore mouth/mouth ulcers
- stomach pain
- trouble sleeping (insomnia)
- back pain
- pain in hands and feet
- dry skin
- hand-and-foot skin-reaction (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red)
- headache
- feeling weak/loss of strength

Less frequent side effects:

- 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

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

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

- irregular heart-beat (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.

Tell your doctor immediately if you get either of these symptoms. These symptoms may persist after you stop taking TYKERB.

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

STORING AND DISPOSING INFORMATION OF TYKERB:

Store at or below 30 °C.

Keep out of the reach of children.

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

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF TYKERB:

TYKERB tablets are supplied in foil-foil (polyamide/aluminium foil/polyvinylchloride (PVC) laminate sealed with aluminium foil lidding) blister strips of 10 tablets, in packs of 70.

Multipacks consist of 2 x 70 tablet packs wrapped together.

Or:

White, round, opaque, high-density polyethylene (HDPE) bottle with a two-piece child-resistant closure (Push & Turn Assembly) in pack size of 70 tablets. The HDPE bottle has an inner heat-seal.

IDENTIFICATION OF TYKERB:

TYKERB Tablets are oval, biconvex, yellow, film-coated tablets, with one side plain and the opposite side debossed with ‘GS XJG’.

REGISTRATION NUMBER:

42/26/0275

NAME AND ADDRESS OF REGISTRATION HOLDER:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

Johannesburg

2090

DATE OF PUBLICATION:

Date of registration: 01 October 2010

Date of the most recently revised package insert as approved by Council: 14 September 2018