

#### Warning

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

## General Information for Patients

**Protocol:**     **Lapatinib (Tykerb<sup>®</sup>) et Capecitabine (Xeloda<sup>®</sup>)**

**Date:** March 2010

**Revision:** November 2015

MEDICATION	ADMINISTRATION
Lapatinib	5 tablets, once a day on an empty stomach, at least 1 hour before or after eating. Take with a glass of water <b>every day without interruption.</b>
Capecitabine	Oral tablets twice a day for 14 days. Tablets should be swallowed with a glass of water within 30 minutes after the end of your breakfast and your supper.  _____ tablets of 500 mg twice daily  _____ tablets of 150 mg twice daily
<b><i>Cycle is repeated every 21 days</i></b>	

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## General Information associated with your treatment

- ❑ These medications are used to prevent the multiplication of abnormal cells and destroy them.
- ❑ A **blood test** will be done prior to every treatment cycle. Depending on its results and side effects of the previous treatment, the dose of medication might be adjusted or treatment might be delayed.
- ❑ You may experience **fatigue** during your treatments. This is usually only temporary and may be related to different reasons (medication, stress, the disease). Maintain a good level of activity but rest when you feel the need to.
- ❑ Your **appetite may diminish**. Eat more often, in smaller quantities.
- ❑ Your **sense of taste may be altered**. Enhance foods with herbs or lemon juice. Eating fruits, chewing non-sugared gums, etc may mask the metallic taste.
- ❑ **Alcohol** (in small quantities) is permitted and will not affect the efficacy of the treatments.
- ❑ You can have an **active sexual** life during your treatments. Your partner will not be exposed to, nor harmed by chemotherapy effects. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress etc.).
- ❑ In **pre-menopausal female patients**, chemotherapy may cause irregularities or cessation of the menstrual cycle during treatments. The menstrual cycle, after stopping chemotherapy, may restart or return to normal. It may also stop permanently. However, a pregnancy remains possible and a method of **contraception** is strongly recommended during treatments. Chemotherapy administered during pregnancy may harm the embryo. Breast-feeding is contra-indicated during treatment.
- ❑ Consult your doctor or pharmacist before you take other medications (even over the counter medications available without a prescription) or natural products. These may provoke an interaction with your treatment and diminish its efficacy, increase its toxicity or bring other significant problems.
- ❑ Follow the instructions given by your cancer center about the right way to handle and dispose of biological fluids (for example urine, stools) in order to protect the environment and your relatives.
- ❑ Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to your doctor and your pharmacist. It is important to make them aware of any change.

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## Adverse Effects and their Management

ADVERSE EFFECTS	MANAGEMENT
<b>Nausea</b> , usually light to moderate, may occur mainly when you are taking Capecitabine.	<ul style="list-style-type: none"><li>• At home, you may also have to take medication to control nausea, as needed.</li><li>• Communicate with a member of your healthcare team if your medication does not relieve your nausea.</li></ul>
Usually there is <b>no hair loss</b> with this treatment	
A decrease in <b>white blood cells</b> might occur will occur during your treatment. You may be at higher risk to contract infections during this period.	<ul style="list-style-type: none"><li>› Wash your hands often.</li><li>› During this period, avoid coming into contact with people who have contagious diseases.</li><li>› Quickly contact a member of your healthcare team if you notice any signs of infection (fever, chills, cough, sore throat, pain while urinating...)</li><li>› Consult your doctor or go immediately to the Emergency Room if you have a fever 38,3 °C (101°F) once or 38 °C (100,4 °F) twice an hour apart.</li><li>› In case of fever, do not take acetaminophen (ex.: Tylenol®, Atasol®) and anti-inflammatory medication (ex.: Motrin®, Advil®).</li></ul>

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<p>You may experience <b>diarrhea</b> which may sometimes become severe, causing <b>dehydration</b> and must be treated rapidly.</p>	<p><b>Diarrhea must be treated with loperamide (Imodium®):</b></p> <p>If diarrhea is light to moderate (less than 4 loose stools per day) :</p> <ul style="list-style-type: none"><li>• Follow the directions written on the package of loperamide. Take 2 tablets first then one tablet after each liquid stool (maximum 8 tablets in a 24 hours period).</li></ul> <p>If you have more than 4 to 6 loose stools a day or if you have nocturnal diarrhea :</p> <ul style="list-style-type: none"><li>• Take 2 tablets at first then one tablet every 2 hours regularly during the day and then 2 tablets every 4 hours regularly at night until feces remain normal for at least 12 hours.</li></ul> <p><b><i>This dosage is much higher than that recommended on loperamide packaging. It is very important that you take loperamide at this high dosage to stop the diarrhea</i></b></p> <p><b>Other actions to take :</b></p> <ul style="list-style-type: none"><li>• <b>Drink lots of fluids (8 to 10 glasses a day unless otherwise instructed by your physician).</b></li><li>• Eat and drink often but in small quantities.</li><li>• Avoid foods that are rich in fibre (cereals, fruits, vegetables, etc.)</li><li>• Contact a member of your healthcare team if the diarrhea does not improve after taking loperamide for 24 hours.</li><li>• If you have diarrhea with fever, contact immediately a member of your health care team and go to the Emergency Room.</li></ul>

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<p><b>Hand and foot syndrome</b> may appear during your treatment. You may experience numbness, tingling, swelling, redness on your hands and feet. Pain, blisters, desquamation may accompany these symptoms.</p>	<p><b>To prevent this syndrome:</b></p> <ul style="list-style-type: none"><li>• Avoid wearing tight clothes or shoes.</li><li>• Wear absorbent sponge rubber soles, and/or gel pads to relieve pressure points.</li><li>• Pat dry your hands and feet rather than rubbing them.</li><li>• Wear light clothing or keep skin free of clothing to avoid perspiring.</li><li>• Wear rubber gloves while washing dishes.</li><li>• Wash your hands and feet in lukewarm water; avoid hot water.</li><li>• Keep your skin well hydrated by regularly using a non perfumed emollient and thick cream.</li><li>• Avoid strenuous exercises or activities that put too much of an ordeal on your hands and feet.</li></ul> <p><b>If symptoms occur:</b></p> <ul style="list-style-type: none"><li>• If these symptoms occur and affect your daily activities, stop taking the medication and notify a member of your healthcare team as soon as possible.</li></ul>

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<p><b>Skins reactions</b> may occur, such as:</p> <p>You might develop a <b>rash</b> mainly on your trunk (chest and back) and sometimes on the face. This reaction looks like acnea.</p> <p>Your skin may become <b>dryer and itchy</b>.</p> <p>Your skin may become more <b>sensitive to the sun</b>.</p>	<p><b>To help prevent or decrease these reactions:</b></p> <ul style="list-style-type: none"><li>• Use fragrance-free, alcohol-free mild soap or cleaning products. Also use bath or shower oils to avoid skin dryness.</li><li>• Moisturize twice a day with fragrance-free, thick, emollient-based creams like Aveeno<sup>MD</sup>, Neutrogena<sup>MD</sup>, handcream, or Vaseline Intensive Care<sup>MD</sup> lotion.</li><li>• Use non perfumed creams and cosmetics without alcohol or colorants. Use a foundation/make up recommended by dermatologists for masking skin problems.</li><li>• Remove make up with a mild cleaning product. Avoid sun exposure.</li><li>• In case of unavoidable sun exposure, wear a hat and clothes with long sleeves.</li><li>• Use a broad-spectrum sunscreen (SPF of 30 or more) up to 2 months after the end of your treatment.</li></ul> <p><b>If despite all these measures, skin reactions appear:</b></p> <ul style="list-style-type: none"><li>• Consult a member of your healthcare team who will recommend appropriate measures.</li></ul>

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<b>Mouth ulcers, redness, pain or swelling in your mouth</b> may appear following your treatment	<ul style="list-style-type: none"><li>• Gently and regularly brush your teeth after each meal and at bedtime.</li><li>• Rinse your mouth with a solution of water and salt with or without baking soda. Gargle 4 times a day – after every meal and at bedtime. Do not drink or eat for one hour after you gargle.</li><li>• Mouthwashes without alcohol found in stores are also useful.</li><li>• If you notice ulcers, redness or painful areas in your mouth, contact a member of your healthcare team..</li></ul>
You may experience <b>shortness of breath, swelling</b> of the ankles and rapid heartbeats.  This could be related to some harmful effects of lapatinib on your heart.	If you notice any one these effects, contact a member of your healthcare team as soon as possible  Furthermore occasionally, you will have to do a test to evaluate your heart.

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## Special Considerations

- Take Capecitabine, as prescribed, twice a day with a glass of water **within 30 minutes after the end of breakfast and supper**. If you forget a dose, take it as soon as possible but do not double your next dose. Try to take capecitabine at the same time every day with the 2 doses 10 to 12 hours apart if possible.
- Take Lapatinib, as prescribed, once a day with a glass of water at least 1 hour before or after eating. If you forget a dose, take it as soon as possible but do not double your next dose. Try to take Lapatinib at the same time every day.
- Avoid eating grapefruit or grapefruit juice, Seville oranges, or star fruit as they could increase the side effects of your treatment
- Tablets must be swallowed whole. Do not chew, split or crush the tablets. If you have trouble swallowing the tablets, talk to your pharmacist who could suggest you appropriate measures.
- Wash your hands immediately after handling your tablets
- Keep your medication at room temperature, out of reach of children and protected from light, heat or moisture.
- Don't throw away unused medication at home. Bring them back to your pharmacy to be destroyed safely.
- There are many drug interactions with your treatment. It is recommended that you consult your pharmacist if you plan to use other medications or natural products.

Pharmacist: \_\_\_\_\_

Phone: \_\_\_\_\_

From \_\_\_\_h to \_\_\_\_h (Monday to Friday)