

Medication Information Sheet

niLOtinib (ne-LOE-ti-nib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Tassigna®

Appearance: capsule in various strengths and colours

What is this medication for?

- For treating chronic myeloid leukemia (CML)

What should I do before I have this medication?

- Tell your doctor and pharmacist if you have or had heart problems (including irregular heart beat), liver disease (including hepatitis), pancreatic or kidney problems, or have any allergies.
- This drug contains a small amount of lactose. If you cannot tolerate lactose or galactose, talk to your doctor.
- People who have cancer or leukemia are at a higher risk of developing other cancers/leukemias (usually some years later) or blood clots. Some cancer medications may increase these risks, especially if used for a prolonged period of time. You should discuss any concerns with your doctor.

How will this medication affect sex, pregnancy and breastfeeding?

- niLOtinib can harm the unborn baby and should not be used by pregnant women.
- If there is ANY chance that you or your partner may become pregnant, you and your partner together must: ► **Use 2 effective forms of birth control at the same time** while taking this drug: Keep using birth control until **4 weeks** after stopping nilotinib. Discuss with your healthcare team.
- Tell your doctor right away if you or your partner becomes pregnant.
- Do not breastfeed while taking nilotinib.
- This medication may affect fertility (ability to get pregnant).

How is this medication given?

- Take it exactly as directed by your doctor.
- Do not crush or open the capsules.
- Swallow whole with a glass of water on an empty stomach, one hour before or two hours after food or other medications. Do not take with meals as this may increase side effects.
- If you have trouble swallowing the capsule, you may open it and mix the content of each capsule

*The most updated version and more symptom control information can be found on: <http://www.cancercare.on.ca/druginfo>

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in 1 teaspoon of applesauce and take right away. Do not mix with other foods/liquids or use more applesauce than recommended.

- If you miss a dose, skip this and take your next dose as you normally do. Do not take an extra dose to make up for the missed dose.

What else do I need to know while on this medication?

- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. They may increase side effects.
- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- For mild aches and pain:
 - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding.
 - Talk to your health care team before you start or stop these medications.
 - If you feel unwell, take your temperature before taking any of these medications. They may hide a fever.
 - **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Avoid alcohol while taking nilotinib as it may make the medicine not work as well.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

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What are the side effects of this medication?

Common side effects usually occur in more than 1 out of every 10 patients. Other side effects are less common, but may be severe. You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
More Common Side Effects	
<p>Rash; dry, itchy skin (may be severe in some cases)</p> <ul style="list-style-type: none"> Stay out of the sun; wear sunblock, a hat and cover exposed skin. Use daily moisturizer. May be severe, including blisters and skin peeling; get emergency medical help right away if this occurs. 	Contact your health care team if no improvement or if severe
<p>Nausea and vomiting (generally mild)</p> <ul style="list-style-type: none"> Drink clear fluids and avoid large meals. Get fresh air and rest. Limit spicy, fried foods or foods with a strong smell. Take anti-nausea drug(s) exactly as directed by your doctor. It is easier to prevent nausea than to treat it. Contact your doctor if nausea lasts more than 48 hours or vomiting for more than 24 hours. Also see Nausea & Vomiting pamphlet.* 	Contact your health care team if no improvement or if severe
<p>Tiredness</p> <ul style="list-style-type: none"> Rest often; take naps if needed. Move slowly when getting up. Eat well-balanced meals and drink plenty of fluids. Light exercise may help. Do not drive a motor vehicle or operate machinery when feeling tired. 	Contact your health care team if no improvement or if severe
<p>Headache; muscle pain</p> <ul style="list-style-type: none"> Take painkiller(s) as directed, if given to you by your doctor. Otherwise, take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. Rest often, but may try light exercise. 	Contact your health care team if no improvement or if severe
<p>Abnormal levels of pancreas tests (lipase, amylase) (may be severe in some cases)</p> <ul style="list-style-type: none"> Your doctor may monitor these regularly. Get emergency help right away if you experience increased pain in the centre of the belly (may extend to your back), with appetite or weight loss. 	Contact your health care team if no improvement or if severe

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More Common Side Effects	
<p><i>Unusual bleeding or bruising</i></p> <p>You may have black stools, cough up blood, blood in your urine, purple or red dots on your skin or bleeding that will not stop.</p> <p><i>Fever, chills, infection</i></p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> • 38.3°C (100.9°F) or higher at any time OR • 38.0°C (100.4°F) or higher for at least one hour. <p>While you are getting chemotherapy treatments:</p> <ul style="list-style-type: none"> • Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills). • Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever. • Do not eat or drink anything hot or cold right before taking your temperature. • Wash your hands often. • Check with your doctor before getting any vaccines, surgeries or visiting your dentist. <p>If you have a fever, talk to your health care team or go to the closest emergency room.</p> <p>See our Neutropenia (Low white blood cell count) pamphlet for more information.</p>	<p>Get emergency medical help right away</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects, but may be Severe	

Side effects and what to do	When to contact doctor?
Less Common Side Effects, but may be Severe	
Heart problems (irregular heartbeat, chest pain, fainting, swelling in leg/ankle/belly, shortness of breath)	Get emergency medical help right away
Mild swelling in arms and legs; puffiness (may be severe in some cases) <ul style="list-style-type: none"> • Keep your feet up when sitting. Eat a low-salt diet. • Avoid tight fitting clothing. 	Contact your health care team if no improvement or if severe
Liver problems (yellow skin or eyes, dark urine)	Get emergency medical help right away
Pancreas problems (increased pain in centre of belly and may extend to back, appetite or weight loss)	Get emergency medical help right away
Blockage / hardening of an artery (blood vessel) in your heart, brain, chest, belly, or limbs; this may result in stroke (sudden loss of vision, speech, or the use of your limb(s)) or heart attack (chest pain, shortness of breath), or pain in chest, belly or limb	Get emergency medical help right away
Decreased blood flow to your leg(s) <ul style="list-style-type: none"> • Due to gradual hardening/narrowing of the arteries in your leg(s); rarely it may affect the arm(s) • Pain, cramping, or tired feeling in leg muscles; worsens with activity such as walking • Leg(s) or feet may feel numb at rest. Skin may look pale and feel cool to the touch. 	
Lung problems (increased cough, breathing problems, chest pain, coughing blood)	Get emergency medical help right away
Blood clot (limb pain or swelling, hardened vein in limb), may occur in lungs (sudden start of coughing, breathing problems, chest pain, coughing blood)	Get emergency medical help right away
Kidney problems (lower back pain, body swelling) <ul style="list-style-type: none"> • Also look for passing little or no urine, or recent unusual weight gain. 	Get emergency medical help right away

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Side effects and what to do	When to contact doctor?
Less Common Side Effects, but may be Severe	
Rupture in stomach or intestine wall (Sudden, severe pain in belly or stomach area)	Get emergency medical help right away
Allergic reaction (severe rash, itchiness, swollen face, lip or tongue, chest or throat tightness; may occur during or shortly after the drug is given)	Get emergency medical help right away
Eye problems (pain, tearing, blurred vision or other unusual changes with your sight)	Contact your health care team as soon as possible
Increased pressure in the lung's blood vessels (chest pain, shortness of breath (worsens with activities), leg swelling)	Get emergency medical help right away
Breakdown of muscle cells, may lead to kidney problems (severe muscle pain or weakness, dark urine)	Get emergency medical help right away
Rapid killing of cancer cells when you start treatment, may lead to build up of cell waste products <ul style="list-style-type: none"> • If mild, this may cause gout, with joint pains, but if severe, may cause fevers, kidney failure, confusion, and be life-threatening. • You MUST take the preventive medicines given by your doctor AND • Drink plenty of fluids (6-8 glasses per day) and void (urinate) frequently. 	Get emergency medical help right away
Inflammation of blood vessels in the brain, kidney, skin or eye	Get emergency medical help right away
Recurrence of Hepatitis B infection (yellowing of white of the eyes or skin, upper right belly discomfort, fatigue, appetite loss, dark urine)	Get emergency medical help right away

For more links on how to manage your symptoms go to www.cancercare.on.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

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A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.