Nilotinib (nil ‘ot’ i nib) is a drug that is used to treat some types of cancer. It is a capsule that you take by mouth.

Blood tests may be taken regularly during treatment. The dose and timing of your nilotinib may be changed based on the test results and/or other side effects.

It is important to take nilotinib exactly as directed by your doctor. Make sure you understand the directions.

Take nilotinib only on an empty stomach (one hour before or two hours after food). Do NOT take with food.

If you miss a dose of nilotinib, skip the missed dose and continue at the time of your next usual dosing time. Don’t take any doses to make up for the missed dose.

If you vomit the dose of nilotinib within 30 minutes of taking it, repeat the dose. Let your doctor know as a medication to prevent nausea may be required for future doses.

Other drugs such as ketoconazole (APO-KETOCONAZOLE®), midazolam (VERSED®), rifampin (RIFADIN®), and warfarin (COUMADIN®) may interact with nilotinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist if you are taking drugs to reduce stomach acid such as famotidine (PEPCID®) or calcium carbonate (TUMS®).

Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with nilotinib.

The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of nilotinib.

Nilotinib may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with nilotinib. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.

Store nilotinib capsules out of the reach of children, at room temperature, away from heat, light, and moisture.

Tell doctors, dentists, and other health professionals that you are being treated with nilotinib before you receive any treatment from them.
Changes in blood counts
Nilotinib may cause temporary changes in your blood counts. Your doctor will be following these changes carefully by performing blood tests. Adjustment of your treatment may be needed in certain circumstances.

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<th>BLOOD COUNTS</th>
<th>MANAGEMENT</th>
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| Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. **When they are low, you are at greater risk of having an infection.** | To help prevent infection:  
- Wash your hands often and always after using the bathroom.  
- Avoid crowds and people who are sick.  
- Call your doctor **immediately** at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. |
| Normal platelets help your blood to clot normally after an injury (e.g., cut). **When the platelet count is low, you may be more likely to bruise or bleed.** | To help prevent bleeding problems:  
- Try not to bruise, cut, or burn yourself.  
- Clean your nose by blowing gently. Do not pick your nose.  
- Avoid constipation.  
- Brush your teeth gently with a soft toothbrush as your gums may bleed more easily.  
Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.  
- Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart).  
- For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable. |
Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

<table>
<thead>
<tr>
<th>SIDE EFFECTS</th>
<th>MANAGEMENT</th>
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| Nausea and vomiting may sometimes occur. | You may be given a prescription for antinausea drug(s) to take before your chemotherapy treatment and/or at home. **It is easier to prevent nausea than treat it once it has occurred**, so follow directions closely.  
• Drink plenty of fluids.  
• Eat and drink often in small amounts. Make sure you are still taking your capsules on an empty stomach (one hour before or two hours after food).  
• Try the ideas in *Practical Tips to Manage Nausea.* |
| Skin reactions such as rash, and itchiness may sometimes occur. | • Moisturizing creams can help reduce skin dryness.  
• If skin reactions persist or get worse, call your doctor  
• If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit. |
| Constipation may sometimes occur. | • Exercise if you can.  
• Drink plenty of fluids.  
• Try ideas in *Food Choices to Manage Constipation.* |
| Diarrhea may sometimes occur. | If diarrhea is a problem:  
• Drink plenty of fluids.  
• Eat and drink often in small amounts.  
• Avoid high fibre foods as outlined in *Food Choices to Help Manage Diarrhea.*  
• **Note:** If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take LACTAID® tablets just before your nilotinib dose. |
| Headache may sometimes occur. | Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. |
| Sugar control may rarely be affected in diabetic patients. | Check your blood sugar regularly if you are diabetic. |
### SIDE EFFECTS

| Fatigue (tiredness) and lack of energy may sometimes occur. | • Do not drive a car or operate machinery if you are feeling tired.  
• Try the ideas in *Fatigue/Tiredness – Patient Handout OR Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.* |
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<td>Hair loss is rare with nilotinib. If you lose hair, it will grow back once you stop treatment with nilotinib. Colour and texture may change.</td>
<td>If hair loss is a problem, refer to <em>Resources for Hair Loss and Appearance Changes – Patient Handout.</em></td>
</tr>
</tbody>
</table>
| Abnormal heart rhythm (QT prolongation) rarely occurs. | Minimize your risk of abnormal heart rhythm by:  
• always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement  
• always taking nilotinib on an empty stomach (not with food)  
• avoiding grapefruit and grapefruit juice |

*Please ask your chemotherapy nurse or pharmacist for a copy.

### STOP TAKING NILOTINIB AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.

### SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- **Numbness or tingling** in feet or hands.
- **Persistent abdominal pain**.
CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Uncontrolled nausea, vomiting, or diarrhea.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Easy bruising or minor bleeding.
- Skin rash or itching.
- For diabetic patients: uncontrolled blood sugars.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR