Afatinib (a fa’ ti nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth. The tablet contains lactose.

Tell your doctor if you have ever had an unusual or allergic reaction to afatinib before taking afatinib.

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

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

Take afatinib on an empty stomach (one hour before or three hours after food).

If you miss a dose of afatinib, take it as soon as you can. If the next scheduled dose is due within 8 hours, skip the missed dose and go back to your usual dosing times.

If you vomit the dose of afatinib, do not take a second dose. Take the next dose as scheduled. Call your doctor during office hours for advice.

Other drugs such as rifampin (RIFADIN®) and ritonavir (NORVIR®) may interact with afatinib. 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 before you start or stop taking any other drugs.

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

Afatinib may harm the baby if used during pregnancy. It is best to use birth control while being treated with afatinib and for 2 weeks after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.

Store afatinib tablets out of the reach of children, at room temperature, away from heat, light, and moisture. Keep tablets in the original blister card inside the aluminum pouch with the desiccant. Once the aluminum pouch has been opened, tablets are stable for 14 days. Return expired tablets to your pharmacy for disposal.

Tell doctors, dentists, and other health professionals that you are being treated with afatinib before you receive any treatment from them.
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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<tbody>
<tr>
<td>Diarrhea commonly occurs.</td>
<td>Diarrhea must be treated immediately with loperamide 2 mg tablets (e.g., IMODIUM®):</td>
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<td>• Take <strong>TWO tablets</strong> at the first sign of loose or more frequent stools than usual.</td>
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<td></td>
<td>• Then take <strong>ONE tablet</strong> with every loose stool, up to a maximum of ten tablets per day. Continue until diarrhea has stopped for 12 hours.</td>
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<td>• <strong>This dose is much higher than the package directions. It is very important that you take this higher dose to stop the diarrhea.</strong></td>
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<td>• Always keep a supply of loperamide (e.g., have 48 tablets at home). You can buy loperamide at any pharmacy without a prescription.</td>
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<td>• To help diarrhea:</td>
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<td>▪ Drink plenty of fluids.</td>
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<td>▪ Eat and drink often in small amounts.</td>
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<td>▪ Avoid high fibre foods as outlined in <em>Food Choices to Help Manage Diarrhea.</em></td>
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<td>▪ A dietitian can give you more suggestions for dealing with diarrhea.</td>
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<td>• If diarrhea does not improve 24 hours after starting loperamide or lasts more than 48 hours, call your doctor.</td>
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<td><strong>Note:</strong> If lactose in milk usually gives you diarrhea, the lactose in the afatinib tablet may make it worse. Take LACTAID® tablets just before your afatinib dose.</td>
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| **Nausea and vomiting** may occur with afatinib. Most people have little or no nausea. | You may be given a prescription for antinausea drug(s) to take 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.  
  - Try the ideas in *Practical Tips to Manage Nausea.* |
| **Skin reactions** such as rash, acne, itchiness, or dryness commonly occur. | Exposure to the sun might make this worse.  
  - Avoid direct sunlight and tanning salons during treatment.  
  - Wear a hat, long sleeves, and long pants outside on sunny days.  
  - Wear a sunscreen that blocks both UVA and UVB and has a sun protection factor (SPF) of at least 30. Apply liberally, 30 minutes before exposure. Reapply every 2 hours and after swimming.  
  - Refer to *Your Medication Sun Sensitivity and Sunscreens* or the BC Health Guide for more information.  
  If your skin reaction is very irritating or gets worse, call your doctor. Otherwise, be sure to mention it at your next visit. |
| **Nail changes**, including loosening or loss of the nail, and swelling commonly occur. |  
  - Avoid trauma to nails or fingertips.  
  - Avoid harsh soaps, detergents and nail products.  
  - Keep hands clean and dry.  
  If nail changes interfere with your activity, or are painful, call your doctor. Otherwise, be sure to mention it at your next visit. |
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| Minor bleeding, such as nosebleeds, may sometimes occur. | • Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat.  
• Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes.  
• After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes.  
• Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped.  
• Get emergency help if a nosebleed lasts longer than 20 minutes. |
| Sore mouth commonly occurs. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection. | • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste.  
• Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day.  
• Try the ideas in Food Ideas to Try with a Sore Mouth.* |
| You may sometimes have trouble sleeping.           | • Talk to your doctor if you continue to have trouble sleeping.  
• This will return to normal when you stop taking afatinib. |
| Loss of appetite and weight loss may sometimes occur. | Try the ideas in Food Ideas to Help with Decreased Appetite.* |
| 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.* |
Hair loss sometimes occurs with afatinib. Hair will grow back once you stop treatment with afatinib. Colour and texture may change.

If hair loss is a problem, refer to Resources for Hair Loss and Appearance Changes – Patient Handout.*

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

STOP TAKING AFATINIB 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); runny nose, cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, cough, swelling of feet or lower legs, or fainting.
- Sudden abdominal pain or tenderness.

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

- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower legs.
- Severe skin reaction, including the areas around the nails, that is painful, red, or swollen.
- Redness, swelling, or pain on the palms of hands and/or soles of feet.
- Changes in eyesight such as eye pain, swelling, redness, blurred vision, or other changes.
- Increased sore throat or mouth that makes it difficult to swallow comfortably.
- Diarrhea that does not improve with loperamide.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Headache or pain not controlled with acetaminophen (e.g., TYLENOL®).
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Constipation, upset stomach, or changes in taste.
- Dizziness.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR