For the Patient:  LUAVAFAT

Other Names: First-line Treatment for Epidermal Growth Factor Receptor (EGFR) Mutation-Positive Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) with Afatinib

LU = Lung
AV = AdVanced
AFAT = AFATinib

ABOUT THIS MEDICATION

What is this drug used for?
Afatinib is a drug given to treat Non-Small Cell Lung Cancer. It is a tablet which is taken by mouth.

How does this drug work?
Afatinib works by interfering with certain enzymes called tyrosine kinases that are important in transmitting the chemical signals needed for essential processes like cell division and replication in cancer cells.

INTENDED BENEFITS

This treatment is being given to slow down the growth of cancer cells in your body. This treatment can help with controlling some of the symptoms the cancer may be causing and may delay or prevent new symptoms from starting.

LUAVAFAT TREATMENT SUMMARY

How is this drug given?
- Afatinib is taken once a day, continuously, as long as you are benefiting from treatment and not having too many side effects.
- Afatinib should be swallowed whole with a glass of water, and should be taken on an empty stomach (1 hour before or 3 hours after food).

What will happen when I get the drug?
- A blood test is done within one month of starting treatment.
- A blood test is also done two weeks after starting treatment and each time you see your oncologist.
- The dose and timing of your treatment may be changed based on your blood test results and/or other side effects.
SIDE EFFECTS AND MANAGEMENT:

- Your oncologist will review the risks of treatment and possible side effects with you before starting treatment.
- The pharmacist will review how to take the medication and possible side effects with you on the day you first pick up your medication.
- Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of. Please refer to the patient information handout entitled “For the Patient: Afatinib” for a complete list of possible side effects and their management.

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<th>SERIOUS SIDE EFFECTS</th>
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| Diarrhea commonly occurs | **Diarrhea must be treated immediately with loperamide 2mg tablets (e.g., IMODIUM®):**  
  - Take **TWO tablets** at the first sign of loose or more frequent stools than usual.  
  - Then take **ONE tablet** with every loose stool, up to a maximum of ten tablets per day. Continue until diarrhea has stopped for 12 hours.  
  - **NOTE:** This dose is much higher than the package directions. It is very important that you take this higher dose to stop the diarrhea.  
  - Always keep a supply of loperamide on hand at home. You can buy loperamide from any pharmacy without a prescription.  
  - If diarrhea does not improve 24 hours after starting loperamide or lasts more than 48 hours, call your oncologist.  
  - NOTE: if lactose in milk usually gives your diarrhea, the lactose in the afatinib tablet may be causing your diarrhea. Take LACTAID® tablets just before your afatinib dose. |
| Heart failure rarely occurs | Tell your doctor as soon as possible if you have shortness of breath, fatigue or leg swelling. Rarely, treatment can result in a failure of the heart’s pumping action. If you are particularly susceptible to this because of medical history and/or other heart medications, your doctor will test your heart function throughout treatment. |
| Lung problems rarely occur | Tell your doctor immediately or get emergency help if you have difficulty breathing, shortness of breath, cough or tightness in the chest. |
## SERIOUS SIDE EFFECTS

| Liver failure rarely occurs | Regular blood tests will be done throughout your treatment to monitor your liver function.  
|                            | See your oncologist as soon as possible if you have signs of liver problems such as yellow eyes or skin, white or clay-colored stools. |

**Stomach or intestine perforation (tear) rarely occurs**

Seek immediate emergency help if you experience severe stomach or abdominal pain, fever, chills or changes in bowel habits.

## OTHER SIDE EFFECTS

| Skin reactions such as rash, acne, itchiness or dryness commonly occur | Exposure to 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 minute before exposure. Reapply every 2 hours and after swimming.  
|                                                                          | If skin reactions are very irritating, contact your oncologist. 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 everyday activities, or are painful, contact your oncologist. Otherwise, be sure to mention it at your next visit. |

## INSTRUCTIONS FOR THE PATIENT

**What other drugs can interact with LUAVAFAT?**

- 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, your dose may need to be changed or your treatment may need to be held for a few days.
- Check with your doctor or pharmacist before you start taking any new prescription or non-prescription drugs.

**Other important things to know:**

- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
• Afatinib may harm the baby if used during pregnancy. It is best to use birth control while you are being treated with afatinib. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
• Tell all doctors or dentists you see that you are being treated with afatinib before you receive any treatment from them.

If you experience symptoms or changes in your body that have not been described in “For the Patient: Afatinib” but worry you, or if any symptoms are severe, contact: ____________________________ at telephone number: ____________________________