

For the Patient: LUAVOSI

Other Names: Treatment of EGFR T790M Mutation-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Osimertinib

LU = LUng
AV = AdVanced
OSI = OSImertinib

ABOUT THIS MEDICATION

What is this drug used for?

Osimertinib is a drug given to treat non-small cell lung cancer that is EGFR T790M mutation-positive. It is a tablet which is taken by mouth.

How does this drug work?

Osimertinib 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.

LUAVOSI TREATMENT SUMMARY

How is this drug given?

- Osimertinib is taken once a day, continuously, as long as you are benefiting from treatment and not having too many side effects.
- Osimertinib may be taken with food or on an empty stomach.

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 each time you see your oncologist.
- The dose of your treatment may be changed based on your blood test results and/or other side effects.

INSTRUCTIONS:

What other drugs can interact with LUAVOSI?

- Other drugs such as rifampin (RIFADIN®) and rosuvastatin (CRESTOR®) may *interact* with osimertinib. 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 new prescription or non-prescription drugs, including natural health products.

Other important things to know:

- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with osimertinib.
- If you miss a dose of osimertinib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
- Osimertinib may damage sperm and may harm the baby if used during pregnancy. It is best to use *birth control* while you are being treated with osimertinib. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Store osimertinib capsules out of the reach of children, at room temperature, away from heat, light and moisture.
- Tell all doctors or dentists you see that you are being treated with osimertinib before you receive any treatment from them.

SIDE EFFECTS AND MANAGEMENT:

- Your [healthcare team](#) will review the risks of treatment and possible side effects with you before starting treatment.
- [A member of your healthcare team](#) 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.

SERIOUS SIDE EFFECTS	MANAGEMENT
<p>Slow or abnormal heart rhythm (QT prolongation) rarely occurs</p>	<p>Minimize your risk of abnormal heart rhythm by:</p> <ul style="list-style-type: none"> • Always checking with your doctor and pharmacist about drug interactions when starting a new medication, herbal product or supplement. • Avoiding grapefruit and grapefruit juice and other similar fruits when taking osimertinib. <p>Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded or dizzy.</p>
<p>Heart failure rarely occurs</p>	<ul style="list-style-type: none"> • Regular heart tests will be done throughout your treatment to monitor your heart function. • Immediately report any signs of heart failure such as shortness of breath, fatigue or leg swelling.
<p>Lung problems rarely occur</p>	<p>Tell your doctor immediately or get emergency help if you have difficulty breathing, shortness of breath, cough or tightness in the chest.</p>
<p>Eye problems rarely occur</p>	<p>Tell your doctor right away if you get any symptoms of eye problems: eye pain, swelling, redness with a gritty feeling, watery eyes, blurred vision, sensitivity to light, sudden changes in your eyesight, or any other changes. You may be at increased risk if you wear contact lenses. Use caution when driving or operating machinery.</p>

OTHER SIDE EFFECTS	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment. If you are vomiting and it is not controlled, you can quickly become dehydrated.</p>	<p>You may be given a prescription for anti-nausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* • Tell your healthcare team if nausea or vomiting continues or is not controlled with your anti-nausea drug(s).

OTHER SIDE EFFECTS	MANAGEMENT
<p>Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* • Tell your healthcare team if you have diarrhea for more than 24 hours.
<p>Constipation may sometimes occur</p>	<ul style="list-style-type: none"> • Drink plenty of fluids. • Exercise if you can. • Try ideas in <i>Food Choices to Manage Constipation</i>.*
<p>Skin rash and dry or itchy skin commonly occur</p>	<ul style="list-style-type: none"> • Moisturizing creams can help reduce skin dryness • Avoid hot showers • Exposure to the sun might make these symptoms worse. Refer to Your Medication Sun Sensitivity and Sunscreens* or the BC Health Guide for more information. • If your symptoms get worse, or are very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
<p>Nail changes, including loosening or loss of the nail, and swelling sometimes occurs</p>	<ul style="list-style-type: none"> • 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.
<p>Sore mouth sometimes 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.</p>	<ul style="list-style-type: none"> • 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 <i>Food Ideas to Try with a Sore Mouth</i>.*
<p>Headache may sometimes occur.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.

OTHER SIDE EFFECTS	MANAGEMENT
Muscle or joint pain may sometimes occur.	<ul style="list-style-type: none"> You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.
Loss of appetite sometimes occurs.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Tiredness and lack of energy may sometimes occur.	<ul style="list-style-type: none"> Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i> .*
Hair loss is rare with osimertinib.	If hair loss is a problem, refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</i> .*

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

STOP TAKING OSIMERTINIB AND CHECK WITH YOUR HEALTHCARE TEAM 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 a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain, or shortness of breath.
- 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.

CHECK WITH YOUR HEALTHCARE TEAM 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.
- **Eye pain**, sensitivity to light, red or itchy eyes, or blurry vision.
- Signs of **bladder problems** such as changes in urination, painful burning sensation, presence of blood, or abdominal pain.

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

- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Easy bruising or minor bleeding.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Dizziness or ringing in your ears.
- Heartburn, hiccups, upset stomach, or changes in taste.
- Muscle spasms or tremors.
- Unusual mood changes or trouble sleeping.
- For diabetic patients: uncontrolled blood sugars.

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact: _____ at telephone number: _____