

For the Patient: ULUAVOSI

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

U = Undesignated (requires special approval)

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.

ULUAVOSI 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.

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: Osimertinib**” for a complete list of possible side effects and their management.

SERIOUS SIDE EFFECTS	MANAGEMENT
Slow or abnormal heart rhythm (QT prolongation) rarely occurs	Minimize your risk of abnormal heart rhythm by: <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. Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded or dizzy.
Heart failure rarely occurs	<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.
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.

OTHER SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur. Most people have little or no nausea.	You may be given a prescription for an anti-nausea drug(s) to take at home. It is easier to prevent nausea than to treat it once it has occurred, so follow directions closely. <ul style="list-style-type: none">• Drink plenty of liquids.• Eat and drink often in small amounts.• Try the ideas in <i>Food Choices to Help Control Nausea</i>

OTHER SIDE EFFECTS	MANAGEMENT
Diarrhea may sometimes occur	To help diarrhea: <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 Ideas to Help Manage Diarrhea</i>.
Constipation may sometimes occur	To help with constipation: <ul style="list-style-type: none"> • Drink plenty of fluids. • Exercise if you can. • Try the ideas in <i>Suggestions for Dealing with Constipation</i>.
Eye problems , such as blurry or double vision, sensitivity to light and redness/itchiness may occur, especially if you wear regular contact lens.	<ul style="list-style-type: none"> • Use caution when driving or operating machinery, especially at night. • Tell your doctor at your next visit, especially if the changes don't go away or get worse.
Skin rash and dry or itchy skin commonly occur	<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.
Nail changes , including loosening or loss of the nail, and swelling sometimes occurs	<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.

INSTRUCTIONS FOR THE PATIENT

What other drugs can interact with ULUAVOSI?

- 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.

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