

Larotrectinib (Vitrakvi)

About This Drug

Larotrectinib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in the number of white blood cells and red blood cells. This may raise your risk of infection and make you tired and weak.
- Decrease in a blood protein called albumin
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Tiredness
- Fever
- Changes in your liver function
- Decreased level of calcium in your blood
- Bone and muscle pain
- Feeling dizzy
- Cough

Note: Each of the side effects above was reported in 20% or greater of patients treated with larotrectinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme dizziness, confusion, have problems with memory, concentration and/or attention, trouble sleeping, and/or changes in mood.
- Severe changes in your liver function
- Risk of bone fractures (i.e., femoral, hip)

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

How to Take Your Medication

- **Capsules:** Swallow the medicine whole with water, with or without food. Do not crush or chew capsules.
- **Oral solution:** Please refer to the package insert for administration instruction.
- Equal doses of the oral solution and capsules can be substituted for each other.
- **Missed dose:** If you miss a dose, and it is less than 6 hours until your next dose, then skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than 6 hours until your next dose, take the missed dose. Do not take 2 doses at the same time or extra doses. Do not replace a vomited dose. If you vomit a dose or miss a dose, contact your doctor.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage: Capsules:** Store capsules in the original container at room temperature.
- **Storage: Oral solution:** Store oral solution in the original bottle in the refrigerator, between 36°F to 46°F (2°C to 8°C). Do not freeze. Opened bottles should be used within 31 days if 50 mL bottle and 90 days if 100 mL bottle.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).



- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation and/or diarrhea.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- If you are dizzy, get up slowly after sitting or lying.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Drug Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of larotrectinib in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with larotrectinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking larotrectinib as this may lower the levels of the drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and/or extreme weakness that interferes with your daily activities
- Agitation, confusion
- Feel irritable, nervous, or restless
- Feel abnormally well
- Lose interest in your daily activities that you used to enjoy and feeling this way every day, and/or you feel hopelessness
- Problems with memory and/or concentration
- Trouble falling or staying asleep
- Feeling dizzy or lightheaded
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable



- Pain in your abdomen that does not go away
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Swelling of the hands, feet, or any other part of the body
- Pain that does not go away, or is not relieved by prescribed medicines
- Changes in your ability to move around or bone abnormalities
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 1 week after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 1 week after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 week after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In women, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on egg banking.

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