

# Larotrectinib

(lar" oh trek' ti nib)

---

**Brand Name(s):** Vitakvii®

## WHY is this medicine prescribed?

Larotrectinib is used to treat a certain type of solid tumors in adults and children 1 month of age and older that have spread to other parts of the body or cannot be treated successfully with surgery. This medication is used only if there are no other treatments available and the tumors have worsened after receiving other treatments. Larotrectinib is in a class of medications called kinase inhibitors. It works by blocking the action of the abnormal protein that tells the cancer cells to multiply. This may help slow the growth of tumors.

## HOW should this medicine be used?

Larotrectinib comes as a capsule and as an solution (liquid) to take by mouth. It is usually taken with or without food twice daily. Take larotrectinib at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take larotrectinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with water; do not chew or crush them.

Use an oral syringe (measuring device) to accurately measure and take your dose of larotrectinib solution. Ask your pharmacist for an oral syringe if one is not included with your medication. Do not use a household teaspoon to measure the solution. Replace each oral syringe after using it for 7 days or if it becomes damaged. Follow the manufacturer's instructions about how to use and clean the oral syringe. Ask your doctor or pharmacist if you have any questions.

If you are giving the solution to a child, place the tip of the oral syringe into the child's mouth against the inside of the cheek. Keep the child in an upright position for a few minutes right after giving a dose

of larotrectinib. If the child spits up a dose or you are not sure the entire dose was given, do not give another dose.

If you vomit immediately after taking larotrectinib, do not repeat the dose. Continue your regular dosing schedule.

Your doctor may need to temporarily or permanently stop your treatment or decrease your dose of larotrectinib during your treatment. This depends on how well the medication works for you and the side effects you experience. Be sure to tell your doctor how you are feeling during your treatment with larotrectinib.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

## Are there OTHER USES for this medication?

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What SPECIAL PRECAUTIONS should I follow?

Before taking larotrectinib,

- tell your doctor and pharmacist if you are allergic to larotrectinib, any other medications, or any of the ingredients in larotrectinib capsules or solution. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: certain antifungals such as itraconazole (Onmel, Sporanox) and ketoconazole; avanafil (Stendra); buspirone; clarithromycin (Biaxin, in PrevPac); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as efavirenz (Sustiva, in Atripla), indinavir (Crixivan), nelfinavir (Viracept), nevirapine (Viramune), ritonavir (Norvir, in

This leaflet does not contain all the possible information about this drug. Your doctor or pharmacist can give you additional information to answer any questions you may have.

**Larotrectinib (continued)**

Kaletra), and saquinavir (Invirase); certain medications that suppress the immune system such as everolimus (Afinitor, Zortress), sirolimus (Rapamune), and tacrolimus (Astagraf, Envarsus XR, Prograf); lovastatin; midazolam; nefazodone; pioglitazone (Actos); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); certain medications for seizures such as carbamazepine (Carbatrol, Epitol, Tegretol, others), phenobarbital, and phenytoin (Dilantin, Phenytek); sildenafil (Revatio, Viagra), simvastatin (Flolipid, Zocor); and vardenafil (Levitra, Staxyn). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with larotrectinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- tell your doctor what herbal products you are taking, especially St. John's wort. Do not take St. John's wort while taking larotrectinib.
- tell your doctor if you have or have ever had conditions that affect the nervous system or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or if you plan on fathering a child. If you are female, you will need to take a pregnancy test before you start treatment and use birth control to prevent pregnancy during your treatment and for 1 week after your final dose. If you are male, you and your female partner should use birth control during your treatment and for 1 week after your final dose. Talk to your doctor about birth control methods that you can use. Larotrectinib may decrease fertility in women. However, you should not assume that you cannot become pregnant. If you or your partner become pregnant, call your doctor immediately. Larotrectinib may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed during your treatment and for 1 week after your final dose.
- you should know that larotrectinib may cause drowsiness, dizziness, or confusion. Do not drive a car or operate machinery until you know how this medication affects you.

**What SPECIAL DIETARY instructions should I follow?**

Do not eat grapefruit or drink grapefruit juice while taking this medication.

**What should I do IF I FORGET to take a dose?**

Take the missed dose as soon as you remember it. However, if it is less than 6 hours before your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**What SIDE EFFECTS can this medicine cause?**

Larotrectinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- cough
- constipation
- diarrhea
- nausea
- vomiting
- stomach pain
- headache
- nasal congestion
- weight gain
- muscle, joint, or back pain
- muscle weakness
- increased thirst; change in the amount or color of urine; dry skin; or fainting

Some side effects can be serious. If you experience any of these symptoms or those in the SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:

- slow or difficult speech; accidental falling; or tingling, numbness, or burning sensation in your hands and feet
- fever
- swelling in hands, feet, ankles, or lower legs

This leaflet does not contain all the possible information about this drug. Your doctor or pharmacist can give you additional information to answer any questions you may have.

**Larotrectinib (continued)**

- shortness of breath
- unusual tiredness or weakness; or pale skin
- loss of appetite; nausea; vomiting; yellowing of the skin or eyes; or pain in the upper right part of the stomach

Larotrectinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

**What should I know about STORAGE and DISPOSAL of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store the capsules at room temperature and away from excess heat and moisture (not in the bathroom). Keep the oral solution in the refrigerator and closed tightly; do not freeze. Dispose of any unused oral solution 90 days after opening the bottle for the first time.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org>

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p>) for more information if you do not have access to a take-back program.

**What should I do in case of OVERDOSE?**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

**What OTHER INFORMATION should I know?**

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during treatment to check your body's response to larotrectinib. For some conditions, your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with larotrectinib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

© Copyright, January 15, 2019.

This leaflet does not contain all the possible information about this drug. Your doctor or pharmacist can give you additional information to answer any questions you may have.