Taletrectinib



Care Team Contact Information:			
Pharmacy Contact Information:			
Diagnosis:			
This treatment is often used for	certain types of lung cancer, but it may also be used for other diagnoses.		
 Your care team will perform a te 	st for an abnormal ROS1 gene to make sure that taletrectinib is right for you.		
Goal of Treatment:			
Treatment may continue until it it.	no longer works or until side effects are no longer controlled.		
Treatment Regimen			
Treatment Name	How the Treatment Works	How the Treatment is Given	
Taletrectinib (ta-leh-TREK-ti-nib): Ibtrozi (ib-TRO-zee)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Capsules taken by mouth.	

Treatment Administration and Schedule:

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- Taletrectinib comes in 200 mg capsules.
- Your dose might differ, but taletrectinib is typically taken as 600 mg (three 200 mg capsules) once a day.
- Taletrectinib should be taken on an empty stomach. Do NOT eat food for at least 2 hours before or 2 hours after taking taletrectinib.
- Take taletrectinib at about the same time each day.
- Swallow taletrectinib capsules whole. Do NOT open, crush, chew or dissolve the capsule before swallowing.
- If you miss a dose or vomit at any time after taking a dose of taletrectinib, take your next dose at your regularly scheduled time the next day. Do NOT take 2 doses at the same time.
- If you take too much taletrectinib, call your care team or go to the nearest hospital emergency room right away.









Storage and Handling of Taletrectinib

- Store taletrectinib at room temperature between 68°F to 77°F (20°C to 25°C) in a dry location away from light.
- Keep taletrectinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused taletrectinib.

Appointments: Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea or vomiting	
nausea or vomiting	
Other	

Common Side Effects

Side Effect	Important Information		
Low White Blood Cell (WBC) Count and Increased	Description: WBCs help protect the body against infections. If yo	u have a low WBC count, you may be at a higher risk of infection.	
	Recommendations:	Talk to your care team if you have:	
	 Wash your hands and bathe regularly. 	 Fever of 100.4 °F (38°C) or higher 	
Risk of	Avoid crowded places.	• Chills	
Infection	 Stay away from people who are sick. 	 Cough 	
		 Sore throat 	
		 Painful urination 	
		 Tiredness that is worse than normal 	
		 Skin infections (red, swollen, or painful areas) 	







Low Red Blood Cell (RBC) Count and	Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale.				
Hemoglobin	Recommendations:	Talk to your care team if you have:			
(Hgb)	 Get 7 to 8 hours of sleep each night. Avoid operating heavy machinery when tired. Balance work and rest, staying active but resting when needed. 	 Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache 			
Nausea and	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.				
Vomiting	 Recommendations: Eat smaller, more frequent meals. Avoid fatty, fried, spicy, or highly sweet foods. Eat bland foods at room temperature and drink clear liquids. If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food. Your care provider may prescribe medicine for these symptoms. 	 Talk to your care team if you have: Vomiting for more than 24 hours Vomiting that's nonstop Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine) Blood or coffee-ground-like appearance in your vomit Bad stomach pain that doesn't go away after vomiting 			
Diarrhea	Description: Diarrhea is when you have loose, watery bowel movements mor urgently.	re often than usual. The need to use the bathroom may occur			
	Recommendations:	Talk to your care team if you have:			
	 Keep track of how many times you go to the bathroom each day. Drink 8 to 10 glasses of water or other fluids every day, unless your doctor tells you otherwise. Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. Stay away from foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods. Your care team may recommend a medicine (such as loperamide) for diarrhea. 	 4 or more bowel movements than normal in 24 hours Dizziness or lightheadedness while having diarrhea Bloody diarrhea 			









Liver Problems	Description: Treatment can harm your liver. This may cause nausea, stomach pain, and bleeding or bruising. It can also turn your skin and eyes yellow and make your urine dark. Lab tests may be performed to monitor liver function.			
	 Talk to your care team if you have: Yellowing of your skin or the whites of your eyes Severe nausea or vomiting Pain on the right side of your stomach area (abdomen) Dark urine (tea colored) Bleeding or bruising more easily than normal 			
High Cholesterol	Description: High cholesterol levels related to treatment mean that these treatments can sometimes increase the amount of cholesterol in your blood. While cholesterol is needed by the body, excessive levels can be harmful and may lead to heart issues.			
Levels	Recommendations:	Talk to your care team if you have:		
	 Adopt a diet low in saturated and trans fats, increase fiber intake, and engage in regular physical activity. Maintain a healthy weight. Get regular cholesterol tests and inform the care team of any significant changes. Do not smoke and limit alcohol consumption. 	 Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain 		
High Triglyceride Levels	Description: Triglycerides are a type of fat found in your blood. Some cance triglycerides usually do not cause symptoms, but very high levels may incre heart problems over time.	••		
	Recommendations:	Talk to your care team if you have:		
	 Talk to your care team as they may have recommendations regarding your physical activity. Eat a healthy diet that is low in fried foods, sweets, saturated and trans fats. Get regular triglyceride tests and inform the care team of any significant changes; they may prescribe medications if needed. Do not smoke and limit alcohol consumption, as both can negatively affect cholesterol levels. 	Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain		









Rash

Description: Rash or itching skin can cause symptoms like redness, swelling, and varying bumps, such as small red spots, welts, or patches.

Recommendations:

- Keep your skin moisturized with creams or lotions to reduce rash and itchiness; wear loose-fitting clothing.
- Avoid perfumes and colognes, as they may worsen rash symptoms.
- Limit time spent in heat to prevent worsening symptoms.
- Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn.
- Wear long-sleeved clothing with UV protection and broad-brimmed hats.
- Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as directed.
- Use lip balm that contains at least SPF 30.
- Avoid tanning beds.
- Your care team may recommend using over-the-counter antihistamines or topical creams.

Talk to your care team if you have:

Rash or itching that continues to worsen









Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Sympton	ms		
Changes in the electrical activity	QT prolongation can cause irregular heartbeats that can be life-threatening. Your care team will do tests before and during your treatment to			
of your heart	Palpitations (rapid or irregular heartbeat)	Irregularly or fast heartbeats		
called QT prolongation	Dizziness	Fainting or near-fainting		
Lung Problems	Cough (with or without mucus)	Chest pain		
	Shortness of breath	• Fever		
High Uric Acid Levels	Your care team will check your uric acid blood level before and during your treatment. Your care team may prescribe medicine to lower uric acid if needed.			
	Red, hot, tender or swollen joints, especially in your big toe	Nausea or vomiting		
	Pain in your stomach area	Pink or brown urine		
Muscle Problems	Taletrectinib can cause muscle pain, tenderness, and weakness with or creatine phosphokinase (CPK), which may be a sign of muscle damage every 2 weeks during the first month and as needed if you experience utreatment. • Muscle pain and swelling, along with weakness • Fever of 100.4°F or higher	e. Your care team will do blood tests to check your CPK blood levels		
Bone Fractures	Bone fractures may happen with or without a fall or other injury.			
	Pain	Bone abnormalities		
	Changes in movement			

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.

If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.









Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may harm an unborn baby.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment and for 3 weeks after your last dose.
 - o If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - o If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment and for 3 weeks after your last dose.
- Do NOT breastfeed during treatment and for 3 weeks after your last dose.

Additional Information

- Tell your care team about all the medicines you take.
 - This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- Do not drink grapefruit juice or eat grapefruit. Grapefruit may increase the amount of taletrectinib in your blood.
- Avoid taking proton pump inhibitors (PPIs) or H2 blocker medicine during treatment. If you take an antacid, take it at least 2 hours before or 2 hours after taking taletrectinib.
- You should **limit your time in the sun** during treatment.

 Taletrectinib may make your skin sensitive to sunlight. Wear a hat and clothes that cover your skin and use sunscreen with sun protective factor (SPF) if you are in the sun during treatment with taletrectinib and for at least 5 days after your last dose of taletrectinib.
- This Patient Education Sheet may not describe all possible side effects.
 Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes	

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Scan the QR code below to access this education sheet.











Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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