Tovorafenib



Care T	eam Contact Information:					
Pharm	acy Contact Information:					
Diagno	osis:					
•	This treatment is often used	for certain types of brain tumors	called gliomas, but it may	also be used for other uses.		
•	Your care team will perform	a test for a certain type of abnorn	nal "BRAF" gene to make	sure that tovorafenib is right f	or you.	
Goal o	of Treatment:					

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
		Tablets taken by mouth.
Tovorafenib (TOH-voh-RA-feh-nib):	Slows down or stops the growth of cancer cells by blocking a specific	OR
Ojemda (oh-JEM-dah)	protein that helps them survive	Suspension taken or given by mouth, or
		through a feeding tube (minimum 12 French).

Treatment Administration and Schedule

- Tovorafenib comes in 1 tablet strength: 100 mg. It also comes as a suspension taken by mouth in 1 strength: 25 mg/mL. Each bottle contains 12 mL of suspension. The suspension is strawberry flavored.
- Take or give tovorafenib 1 time each week.
- Take or give tovorafenib with or without food.
- If you miss a weekly dose of tovorafenib by:
 - o 3 days or less, take or give the missed dose as soon as you remember. Take or give the next dose on the next regularly scheduled day.
 - o more than 3 days, skip the missed dose and take or give the next dose on the next regularly scheduled day.

Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

• If vomiting happens right after taking a dose, take or give the dose again. If you are not sure if you should take or give another dose, contact your care team.









Treatment Administration and Schedule (Continued)

Tablets:

Swallow tablets whole with water. Do not chew, cut, or crush the tablets.

Suspension:

- See the "Instructions for Use" that comes with your prescription for instructions on how to prepare, measure, and take or give a dose. If you have any questions, talk to your care team.
- The suspension can be taken or given by mouth, or through a feeding tube (minimum 12 French).
- Your or your child's dose may require preparing 2 bottles of the oral suspension.

Below is a blank calendar that can be filled out by you and your care team. Mark the day of the week that you will take or give tovorafenib.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1							
Week 2							
Week 3							
Week 4							

Storage and Handling of Tovorafenib

- Tablets:
 - o Store tablets at room temperature between 68°F to 77°F (20°C to 25°C).
 - Keep tablets in their original package. Tablets should not be removed from blister cards until right before use.
- Suspension:
 - Store the glass bottle containing the oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
 - o Do not use the suspension if the safety seal under the cap is broken or missing.
 - o Throw away your bottle(s), including any unused or expired suspension, oral dosing syringe after taking or giving a dose.
 - See the "Instructions for Use" that comes with your prescription for instructions on when to throw away your bottle(s), including any unused or expired suspension, oral dosing syringe after taking or giving a dose.
- Keep tovorafenib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused tovorafenib.

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 and vomiting	
nausea and vomiting	
Other	

Common Side Effects

Side Effect	Important Information				
Low Red Blood Cell (RBC)	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 appear pale.				
Count and Hemoglobin (Hgb)	Recommendations: 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.	 Talk to your care team if you have: Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache 			
Bleeding Problems	 Description: Treatment may increase your risk of bruising or bleeding. Recommendations: Blow your nose gently; avoid picking it Brush gently with a soft toothbrush and maintain good oral hygiene Use an electric razor for shaving and a nail file instead of clippers Avoid activities that could cause cuts, falls, or injury; wear shoes to protect your feet If a nosebleed occurs, sit up, lean forward, and pinch the soft part of the nose for 10–15 minutes. Prevent straining with bowel movements (your care team may recommend other medicines for this, if needed). Talk with your care team or dentist before medical or dental procedures. 	 Talk to your care team if you have: Nosebleed lasting over 5 minutes despite pressure Cut that continues to bleed Significant gum bleeding when brushing or flossing New or worsening bruises or small red/purple skin spots Severe headache, confusion, fainting, vision changes, or weakness on one side Blood in urine or stool, black/tarry stools Coughing up bright red blood Vomiting blood or material that looks like coffee grounds Heavy menstrual bleeding Any fall or hit to your head 			







Fever	Description: Fever is common with this treatment.	Y
	Recommendations:	 Talk to your care team if you have: Fever of 100.4°F (38°C) or higher Fever lasting for more than 3 days Any signs of infections, such as persistent cough, shortness of breath, or pain
Viral Infections	Description: Viral infections are common with this treatment. Recommendations: Wash your hands and bathe regularly. Avoid crowded places. Stay away from people who are sick.	 Talk to your care team if you have: Fever of 100.4 °F (38°C) or higher Chills Cough Sore throat Tiredness that is worse than normal
Nausea and Vomiting	 Description: Nausea is an uncomfortable feeling in your stomach or the need 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 team may prescribe medicine for these symptoms. 	d to throw up. This may or may not cause vomiting. 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
Constipation	Description: Constipation means having a hard time passing stools or not go which can make you uncomfortable or hurt. Recommendations: • Keep track of how many times you move your bowels every day. • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Exercise regularly. • Eat high-fiber foods like raw fruits and vegetables. • Your care team may recommend medicine (such as polyethylene glycol 3350 or senna) for constipation.	Talk to your care team if you have: Constipation that lasts 3 or more days Constipation after 48 hours, even after using a laxative









	 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 	
Acne-like Rash	Description: An acne-like rash is a skin condition. It usually appears on the fa	ace, neck, and back, causing red, inflamed bumps that may itch or
and Sensitivity to the Sun	feel dry.	— III .
to the oun	Recommendations:	Talk to your care team if you have:
	Your care team may prescribe medicine for rash. If you got a rook, look the area of any and draw. If you got a rook look are the area of any and draw. If you got a rook look are the area of any and draw. If you got a rook look are the area of any and draw. If you got a rook look are the area of a rook and draw. If you got a rook look are the area of a rook and draw.	Painful or worsening rash Pack that does not invested with the street.
]	If you get a rash, keep the area clean and dry.Check with your care team before using any treatments.	 Rash that does not improve with treatment
	 Check with your care team before using any treatments. Do not use over-the-counter acne treatments like benzoyl peroxide 	
]	or salicylic acid, or soaps with alcohol.	
]	Wash with a mild, moisturizing soap, and avoid long, hot baths or	
]	showers.	
]	 After washing, pat your skin dry instead of rubbing. 	
]	 Oatmeal baths and unscented moisturizers may relieve itching. 	
	 Sunlight can worsen symptoms, so avoid sun exposure whenever possible. 	
	 Wear long-sleeved clothing with UV protection if possible. 	
]	 Use broad-brimmed hats for added protection. 	
	Apply broad-spectrum sunscreen (UVA/UVB, at least SPF 30) as	
]	directed.	
]	Use lip balm with at least SPF 30.Avoid tanning beds.	
	Avoid tairing beds.	
Hair Color	Description: Treatment may cause changes in hair color. Hair usually returns	s to normal after treatment, but for some, the change may be
Changes	permanent.	
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Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness.					
	 Recommendations: Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you. Ask your family and friends for help with daily tasks and emotional support. Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good. Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep. Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents. 	 Talk to your care team if you have: Tiredness that affects your daily life Tiredness all the time, and it doesn't get better with rest Dizziness and weakness, along with being tired 				
Headache	 Description: A headache can cause you to feel pain or discomfort in your head Recommendations: Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches. Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches. Apply a cold or warm compress to your forehead or neck to help ease headache pain. Get adequate sleep (7-8 hours per night) and establish a regular sleep schedule. Limit caffeine intake. Your care team may recommend medicine for headaches. 	ad, making it hard to concentrate or feel your best. Talk to your care team if you have: Severe headache More frequent headaches Dizziness or light-headedness Confusion Vision changes				
Slowed Growth in Children	Description: Treatment may cause slowed growth in children. Growth will be	regularly checked during treatment.				









Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms				
Mouth Sores	 Painful sores or ulcers in the mouth and throat Difficulty swallowing Dry mouth 	 Redness and swelling of the mouth or throat Bleeding Changes in taste 			
Diarrhea	Diarrhea (loose stools) or more frequent bowel movements than usual Stool that are black, tarry, sticky, or have blood or mucus	Severe stomach-area (abdominal) pain or tenderness			
Swelling or Fluid Retention	 Swelling that suddenly worsens or spreads to other areas Pain, redness, or warmth in the affected area Signs of shortness of breath or difficulty breathing 	 Swelling is persistent and does not improve with home management Unexpected weight gain 			

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.
 - o If you are able to become pregnant, take a pregnancy test before starting treatment.
 - o Use an effective method of birth control during treatment and for 28 days after your last dose.
 - Birth control methods that contain hormones (such as birth control pills, injections, or transdermal systems) may not work as well during treatment and you could become pregnant. You should use another nonhormonal, effective method of birth control during treatment.
 - 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 2 weeks after your last dose.
- Do NOT breastfeed during treatment and for 2 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.
- The most **common severe abnormal blood tests** include decreased phosphate, decreased red and white blood cells, increased creatine phosphokinase, increase in liver function test, decreased albumin, decreased potassium, and decreased sodium.
- 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.

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