

Enfortumab Vedotin and Pembrolizumab

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra). However, it may also be used for other diagnoses.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until 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
Enfortumab Vedotin (en-FOR-too-mab veh-DOH-tin): Padcev (PAD-sev)	Stops cancer cell growth by targeting a protein and delivering medicine directly to the cancer cell.	Infusion given into a vein.
Pembrolizumab (pem-broh-LIH-zoo-mab): Keytruda (kee-TROO-duh)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion given into a vein.

Treatment Administration and Schedule: Treatment is typically repeated every 3 weeks. This length of time is called a “cycle”.

- Enfortumab vedotin is given on days 1 and 8.
- Pembrolizumab is given on day 1.

Treatment Name	Cycle 1										Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	...	Day 21	Day 1
Enfortumab Vedotin	✓							✓			✓
Pembrolizumab	✓										✓

Appointments: Appointments may include regular check-ups with your care team, treatment appointments, 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 Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting		
To help prevent eye problems		
Other		

Common Side Effects

Side Effect	Important Information
Skin Reactions (Enfortumab Vedotin Boxed Warning)	Description: Skin reactions, including severe skin reactions, have happened in people who have received this treatment. Most severe skin reactions occurred during the first cycle of treatment but may happen later. Your care team will monitor you, may stop your treatment completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. 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 medicines for symptoms. Talk to your care team if you have: - Target lesions (skin reactions that look like rings) - Rash or itching that continues to get worse - Blistering or peeling of the skin - Painful sores or ulcers in mouth or nose, throat, or genital area - Fever or flu-like symptoms - Swollen lymph nodes
Low White Blood Cell (WBC) Count and Increased Risk of Infection	Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection. Recommendations: - Wash your hands and bathe regularly. - Avoid crowded places. - Stay away from people who are sick. - Your care team may prescribe a drug that promotes the growth of WBCs. Talk to your care team if you have: - Fever of 100.4 °F (38°C) or higher - Chills - Cough - Sore throat - Painful urination - Tiredness that is worse than normal - Skin infections (red, swollen, or painful areas)

Low Platelet Count	Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs. • Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment. Talk to your care team if you have: • Nosebleed lasting over 5 minutes despite pressure • Cut that continues to bleed • Significant gum bleeding when flossing or brushing • Severe headaches • Blood in your urine or stool • Blood in your spit after a cough
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	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. 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
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

Diarrhea	Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently. Recommendations: • 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. • Avoid eating 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 medicine (such as loperamide) for diarrhea. Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause 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 team 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

Low Appetite	Description: Treatment can cause a low appetite, which means you may not feel like eating much. It's important to eat enough so your body gets the nutrients it needs to heal and stay strong. Eating healthy foods helps you feel better and recover faster. Recommendations: • Be as active as possible. Do some physical activity before a meal. Before starting an exercise program, talk with your care team. • Take note of the times during the day when your appetite is best. Do not limit food when your appetite is good. Eat your largest meal when you feel the most hungry, whether it is breakfast, lunch, or dinner. • Eat 5-6 small meals per day and snack anytime. • Choose foods high in protein, such as beans, chicken, fish, meat, yogurt, tofu, and eggs. During meals, eat high-protein foods first. • Choose foods that are high in calories. Do not select foods that are labeled "low-fat," "fat-free" or "diet." • If you feel full quickly when eating, do not drink any liquids 30 minutes before a meal so you have more room for solid food. Then, drink liquids between meals. Choose liquids with extra calories, not diet drinks. • Eat a bedtime snack. Choose something easy to digest, such as peanut butter and crackers. If you tend to experience reflux or heartburn, eat at least an hour before lying down. • If food is not appealing, try a nutritious beverage, such as a high-protein shake or smoothie, instead of solid food. • Ask your care team to recommend a liquid nutrition supplement. Add a scoop of protein powder, yogurt, or ice cream for added protein and calories. Talk to your care team if you have: • Weight loss • No appetite • Tiredness
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High Blood Sugar	Description: An increase in blood sugar is common during treatment. Severe high blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have happened in people with and without diabetes, treated with treatment. Recommendations: • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. Talk to your care team if you have: • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar
Eye Problems	Description: Eye problems are common with this treatment. Recommendations: • You may use artificial tear substitutes to help prevent or treat dry eyes. Talk to your care team if you have: • Dry eyes • Increased tears • Blurred vision • Vision changes
Hair Loss	Description: Hair loss or hair thinning can start days to a few weeks after treatment begins, but it usually grows back later. It might be a different texture or color when it comes back and may not look the same as before. Recommendations: • You can wear scarves, hats, or wigs, and think about getting a short haircut before treatment. • Keep your head covered to protect it from the sun and keep it warm. • If your scalp isn't covered outside, remember to put sunscreen on it. Talk to your care team if you would like a wig prescription.

Nerve Problems in Your Arms, Hands, Legs, or Feet	Description: Nerve pain and tingling are uncomfortable sensations caused by nerve damage or irritation. Pain may be sharp, burning, or deep, while tingling feels like pins-and-needles or mild electric shocks, often in the hands, feet, arms, or legs. Recommendations: - Track your pain levels, sensations, and any triggers or factors that make the pain worse or better. - Check your feet daily for any injuries or changes, especially if you have numbness or tingling that affects your feeling. - Your care team may prescribe or recommend medicine for symptoms. Talk to your care team if you have: “Pins and needles” or burning feeling in your hands or feet - Trouble moving your arms or legs - Trouble keeping your balance
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Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Lung Problems	- Cough - Shortness of breath	Chest pain
Liver Problems	- 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
Kidney Problems	- Decrease in your amount of urine - Blood in your urine	- Swelling of your ankles - Loss of appetite
Hormone Gland Problems	- Headaches that will not go away or unusual headaches - Eye sensitivity to light - Eye problems - Rapid heartbeat - Increased sweating - Extreme tiredness - Weight gain or weight loss - Feeling more hungry or thirsty than usual	- Urinating more often than usual - Hair loss - Feeling cold - Constipation - Your voice gets deeper - Dizziness or fainting - Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
Problems in Other Organs and Tissues	- Chest pain, irregular heartbeat, shortness of breath, swelling of ankles - Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs	Persistent or severe muscle pain or weakness, muscle cramps
Extravasation	Extravasation happens when medicine that is supposed to go into a vein leaks out into the tissues around it. This can cause pain, swelling, and damage to the skin and tissues. - Pain, burning, or stinging at the infusion site - Swelling, redness, or blistering around the site	
Infusion Reactions	- Chills or shaking - Itching, rash, or flushing - Trouble breathing or wheezing; tongue-swelling	- Dizziness or feeling faint - Fever of 100.4°F (38°C) or higher - Pain in your back or neck

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, 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 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, for 2 months after your last dose of enfortumab vedotin, and for 4 months after your last dose of pembrolizumab.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment and for 4 months after your last dose of enfortumab vedotin.
- **Do NOT breastfeed** during treatment, for 3 weeks after your last dose of enfortumab vedotin, and for 4 months after your last dose of pembrolizumab.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **3 weeks** after each dose of **enfortumab vedotin**:

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

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.
- **Tell your care team about all your health problems.**
This includes issues with your immune system, like Crohn's disease, ulcerative colitis, or lupus. Also, tell them if you have had an organ transplant, like a kidney or eye transplant. Let them know if you had a stem cell transplant from a donor, had radiation to your chest, or have a nerve problem like myasthenia gravis or Guillain-Barré syndrome.
- **Your treatment might cause side effects that need medicine or a break from treatment.**
Your care team may give you corticosteroids or hormone medicines to help. Sometimes, they may need to delay or stop your treatment if you have certain side effects.
- **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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PES-523