





ENFORTUMAB VEDOTIN

Name of the regimen and cancer drugs

Enfortumab vedotin (en-FOR-too-mab veh-DOH-tin): Padcev®

Common uses

Enfortumab vedotin is most commonly used for urothelial cancer but may be used for other diagnoses.

Treatment schedule

Your treatment will be given into your vein through an intravenous (IV) line. This may be into a short, flexible temporary catheter in your arm, or through a central venous catheter. A central venous catheter, or central line is a long, flexible IV tube that empties into a very large vein next to the heart. Talk with your care team to see which will be best for you and your treatment.

Each enfortumab vedotin treatment is repeated every 28 days. This is known as one cycle. Your treatment may be given for a set number of cycles, or it will keep going until the drug stops working or you have side effects which stop you from continuing treatment.

Enfortumab vedotin IV given on Day 1, 8 and 15

| Drug Cycle 1 | Day 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 15 | 28 | Cycle 2 Day 1 |
|--------------------|-------|---|---|---|---|---|---|---|---|----|--------|--------|---------------|
| Enfortumab vedotin | | | | | | | | | | | | | |

Other medications

Other medications may be ordered for you to prevent or treat certain side effects. These include:

| | Instructions: |
|----------------------------|---|
| Anti-nausea medications | You will receive medications to prevent nausea just before your cancer treatment. You may also get prescriptions for other medications to take at home, as below: |

Possible drug interactions

- Enfortumab vedotin may interact with other drugs you are taking. Please inform your care providers of all prescription medicine, over-the-counter medications, vitamins, and herbal products that you take.
- Talk with your care provider or pharmacist before taking new medications, supplements, or receiving any vaccines.
- Grapefruit or grapefruit juice may interact with enfortumab vedotin. Avoid eating or drinking these during your treatment







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Common Side Effects

Common side effects that have been known to happen in patients receiving enfortumab vedotin are listed in the left side of this table. In some instances, the side effects may be reported less often but are still important to discuss. This table does not list all the known side effects for this therapy, only the ones that are experienced most often. Not every patient experiences every known side effect of a drug; even if you are taking the same drug as another patient, you may experience different side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

| Possible Side Effect | Management |
|---|---|
| Decreased white | Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection. |
| | Wash your hands often, especially before eating and after using the bathroom. Avoid crowds and people with fevers, flu, or other infection. Bathe often for good personal hygiene. |
| blood cells (WBCs) and increased risk for infection | Contact your care team if you experience any signs or symptoms of an infection such as: |
| infection | Fever (temperature more than 100.4°F or 38°C) Chills Sore throat Burning when peeing Tiredness that is worse than normal A sore that becomes red, is draining, or does not heal. |
| | Check with your care team before taking any medicine for a fever or chills. |
| Decreased hemoglobin, part of the red blood cells that carry iron and oxygen | Your hemoglobin should be checked by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily. |
| | Try to get 7 to 8 hours of sleep per night Avoid operating heavy machinery if you feel too tired Find a balance between "work" and "rest" Stay as active as possible, but know that it is okay to rest as needed, too You might notice that you are more pale than usual Let your care team know right away if you have: |
| | Shortness of breath Dizziness Fast or abnormal heartbeat |
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| Possible Side Effect | Management |
|---|--|
| Rash or itchy skin | Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness and wear loose fitting clothing. Avoid using perfumes and cologne as these products may increase rash symptoms. Avoid being in the heat for long periods of time. Your provider may recommend an over-the-counter antihistamine or a topical cream. Sunlight can make symptoms worse Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultra-violet) radiation occurs between the hours of 10am and 4pm. Wear long-sleeved clothing, with UV protection if possible. Wear broad-brimmed hats. Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. Use lip balm with at least SPF 30 If your rash or itching continues to worsen, contact your care team. |
| Fatigue | You may be more tired than usual or have less energy. Stay as active as possible, but know it is okay to rest as needed. Try to do some type of moderate activity every day. Conserve your energy. Plan your activities and do them at a time of day when you feel a bit more energetic. Follow a healthy diet and stay hydrated. Accept help from family and friends Find healthy ways to manage stress, such as meditation, journaling, yoga, and guided imagery Develop good sleeping habits, limit napping during the day to help you sleep better at night. Avoid operating heavy machinery if you feel too tired. |
| Numbness or tingling in hands and feet. | Report changes in your sense of touch, such as a burning feeling, pain on the skin or weakness. Notify your care team as soon as these symptoms develop. Early intervention can limit or resolve these symptoms, but if not addressed these symptoms may become permanent. |
| | Continued on the next page |







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| Possible Side Effect | Management |
|--------------------------------------|---|
| Hair loss (alopecia) | Hair will likely grow back after treatment is completed, although the color and/or texture may be different. It may take 3 to 6 months after therapy is completed to resume normal hair growth. Some people choose to wear scarves, caps, or wigs. A short haircut prior to treatment may help with stress of hair loss. Partial or complete hair loss is likely, usually 1-2 weeks after start of therapy. This hair loss can be all body hair. Be sure to keep your head covered to protect it from the sun during the summer and cold during the winter. If not covering your scalp during the summer months, be sure to use sunscreen when spending time outdoors. |
| Decreased appetite or weight loss | Talk to your care team if you notice a weight loss while taking this medication. When you do not feel like eating, try: Small frequent meals instead of 3 large meals each day. Keep snacks nearby so you can eat when you feel hungry. Liquid nutritional supplements. Drink 8-10 glasses of water or fluid each day, especially if you are not eating, unless your care team has instructed you to limit your fluid intake. |
| Taste changes | Some people may have a metallic or bitter taste in their mouth. To help with taste changes: Choose and prepare foods that look and smell good to you. Use plastic spoons, forks, or knives if food tastes like metal. Flavor foods with spices or juices to change taste. Suck on mints or chew gum to mask taste. Brush teeth before and after eating with a soft bristle toothbrush. Avoid smoking. Notify your doctor if you are having trouble eating or are losing weight. |
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| Possible Side Effect | Management |
|---|---|
| Changes in electrolyte levels and other laboratory values: Low phosphate levels High glucose levels | Changes in some lab values may occur and will be monitored by a simple blood test. You may not feel any symptoms if the changes are mild and they usually are not a sign of a serious problem. More severe changes may occur, which can be a sign of a serious problem. Notify your care team if you have any of the following: Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of your legs or feet Red or brown colored urine |
| Diarrhea (loose and/ or urgent bowel movements) | Monitor how many bowel movements you have each day. Drink 8-10 (8-ounce) glasses of water or fluid each day unless your care team has asked you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). Avoid high fiber foods, such as raw vegetables and fruits and whole grains. Avoid foods that cause gas, such as broccoli and beans. Avoid foods with lactose, such as yogurt and milk. Avoid spicy, fried, and greasy foods. Contact your care team if: The number of bowel movements you have in a day increases by 4 or more You feel dizzy or lightheaded Talk with your care team if you believe you have diarrhea. They may recommend an over-the-counter medication or prescribe something to help keep it under control. |
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| Possible Side Effect | Management | | |
|----------------------|---|--|--|
| Nausea or vomiting | Take all medications as prescribed to help prevent and lessen symptoms of nausea and vomiting. Eat and drink slowly. Drink 8-10 (8-ounce) glasses of water and/or fluid (soup or broth) each day unless your care team has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland foods; avoid spicy, fried, and greasy foods. Avoid intense exercise immediately after eating. Don't lay down right away after eating. Wear loose fitting clothing for comfort. Avoid strong odors. Consider getting fresh air and try deep breathing. Let your care team know if you have nausea or vomiting. Your care team may prescribe medication to help with the symptoms. | | |
| Eye changes | This medication may cause blurred vision, dry eyes, or eye pain. This medication may cause lacrimal duct stenosis, visual changes, watery eyes, light sensitivity Report changes in eyesight to your care team. | | |

Rare but serious side effects

Tell your care provider if you experience any symptoms of these problems:

- Enfortumab vedotin may result in toxicity to the skin. Please notify your healthcare provider if you have any signs of acnelike rashes (skin that is scaly, dry, cracking, or inflamed), skin infections, and or eye infections/loss of vision.
- Enfortumab vedotin may result in extremely high blood glucose levels that could require can progress to a condition called diabetic ketoacidosis (DKA), even in patients who have not previously been told they have diabetes. Your care team will regularly monitor your blood glucose levels. Notify your care team right away for unusual weakness or fatigue, increased thirst, frequent urination, or blurred vision.
- Enfortumab vedotin may irritate your veins as it is infused. Notify your nurse right away if you notice any pain, aching, burning, itching, swelling, or redness at the site of your IV.
- Enfortumab vedotin can cause lung and breathing problems. Tell your care team right away if you have new or worse cough, shortness of breath, chest pain, or difficulty breathing or wheezing.
- Enfortumab vedotin may be harmful to your eyes. Be sure to inform your care team of any issue you have with your vision or pain in your eyes. Your provider may stop treatment with enfortumab vedotin if your eyes are affected.

If you experience ANY new, worsening, or uncontrolled side effects, call your care team immediately.







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Handling body fluids and waste

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Association of Community Cancer Center

Some of the drugs you receive may be present in urine, stool, sweat, or vomit for many days after treatment. Many cancer drugs are toxic, your bodily waste may also be toxic and can be dangerous to come into contact with. Once you have started enfortumab vedotin, follow the instructions below for at least two days after your treatment. This is to keep you, your loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
- If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surface after every use before other people use the toliet.
- □ Wash hands with soap and water after using the toilet for at least 20 seconds.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- □ Wash any skin that has been exposed to body waste with soap and water.
- □ Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- □ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Intimacy, sexual activity, contraception, and fertility

This treatment may cause changes that can affect intimacy and sexuality, including desire and body image. Maintaining physical closeness and/or intimacy with loved ones can be continued during treatment. Holding hands, hugging, and kissing can be done safely. It is recommended that you talk to your care team about any restrictions or questions you may have.

Some treatments can influence the ability to have children, also known as fertility. If you're interested in preserving fertility, talk to your care team before treatment. Ask your healthcare provider to determine when it is safe to become pregnant after your treatment. Patients of reproductive ability should not become pregnant or get their partners pregnant while receiving enfortumab vedotin. Some of the drugs you receive may be present in semen and vaginal secretion for many days after treatment. You should use barrier devices, such as condoms, during sexual activity to limit exposure to body fluids.

- Talk to your care team about birth control. Not all options may be right for your treatment or cancer. Effective contraception could include one or more of the following: barrier methods (e.g. condoms), hormone methods (e.g. birth control pills), or surgery.
- **Tell** your care team if you become pregnant or plan to breastfeed.





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Additional resources

Product website: https://www.padcev.com/ Prescribing information link: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://astellas.us/docs/ PADCEV_label.pdf

Additional instructions

Important notice:

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Permission

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