



For the Patient: GUAVEV

Other Names: Palliative Therapy for Urothelial Carcinoma
Using Enfortumab Vedotin

GU = **GenitoUrinary** (Tumor group)
AV = **Advanced** (Palliative Therapy)
EV = **Enfortumab Vedotin**

ABOUT THIS MEDICATION

What is this drug used for?

- Enfortumab vedotin is a drug that is used to treat cancer in the bladder or urinary tract that cannot be removed by surgery. It is given to patients who have already been treated with chemotherapy and immunotherapy.

How does this drug work?

- Enfortumab vedotin (en fort' ue mab ve doe' tin) is made up of a monoclonal antibody, a type of protein designed to target cancer cells, and a second drug which is intended to kill cancer cells.

INTENDED BENEFITS

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay or prevent the onset of new symptoms.
- It may take several treatments before your doctor can judge whether or not this treatment is helping.

TREATMENT SUMMARY

How is this drug given?

- Enfortumab vedotin will be given to you through the vein (intravenously, IV). This treatment is repeated each week for 3 weeks in a row, followed by one week of rest. This 28 day period of time is called a “cycle”.

The calendar on the next page outlines your treatment plan.

Cycle 1:

	DATE	TREATMENT PLAN
C Y C L E 1		▶ Week 1 → Day 1: enfortumab vedotin
		Week 2 → Day 8: enfortumab vedotin
		Week 3 → Day 15: enfortumab vedotin
		Week 4 → No treatment

This treatment will repeat every 4 weeks. It will continue as long as it is helping, as determined by your oncologist.

What will happen when I get my drugs?

- During the first cycle, a **blood test** will be done before each dose of enfortumab vedotin. After the first cycle, a blood test will be scheduled before the first dose in each cycle (before day 1 only). The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.
- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your treatment plan and will discuss with you how to manage them. *It is a good idea to bring someone with you to your first chemotherapy appointment.*
- You may be given a prescription for anti-nausea medications (to be filled at your regular pharmacy). Please bring your anti-nausea medications with you for each treatment. Your nurse will tell you when to take the anti-nausea medication.
- You may also need to take your anti-nausea drugs at home after therapy. It is easier to prevent nausea than to treat it once it has occurred, so follow directions closely.
- Other drugs may **interact** with enfortumab vedotin. Tell your healthcare team if you are taking any other drugs, as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of enfortumab vedotin.
- Enfortumab vedotin may affect **fertility** in men. If you plan to have children, discuss this with your doctor before being treated with enfortumab vedotin.
- Enfortumab vedotin may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with enfortumab vedotin. Ask your doctor how long you should continue using birth control after your treatment has ended. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for at least 6 months after your treatment has ended.
- **Tell** your doctor, dentist, and other health professionals that you are being treated with enfortumab vedotin before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
<p>Allergic reactions may rarely occur. Signs of an allergic reaction may include flushing, rash, itching, dizziness, swelling or breathing problems.</p>	<p>Tell your nurse if this happens while you are receiving enfortumab vedotin or contact your oncologist immediately if this happens after you leave the clinic.</p>
<p>Enfortumab vedotin burns if it leaks under the skin.</p>	<p>Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given.</p>
<p>Pain or tenderness may occur where the needle was placed.</p>	<p>Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</p>
<p>Nausea and vomiting may occur after your treatment. If you are vomiting and it is not controlled, you can quickly become dehydrated. Most people have little or no nausea.</p>	<p>You may be given a prescription for antinausea drug(s) to take before your treatment. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* <p>Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).</p>
<p>Skin rashes may commonly occur.</p>	<p>If itching is very irritating or your skin blisters or peels, call your healthcare team. Otherwise, be sure to mention it at your next visit.</p>
<p>Sugar control may often be affected, even if you don't have diabetes.</p>	<ul style="list-style-type: none"> • Tell your healthcare team immediately if you feel more thirsty than normal or you are urinating (going pee) more often. • Check your blood sugar often if you have diabetes. Tell your healthcare team if your blood sugars are not controlled. • If you don't have diabetes, ask your healthcare team for advice about checking your blood sugar. • Get emergency help if you have high blood sugar and you are confused, feel weak or tired, have stomach pain or feel like vomiting, or have fruity-scented breath.

SIDE EFFECTS	MANAGEMENT
<p>Numbness or tingling of the fingers or toes may often occur. This will slowly return to normal once your treatments are over. This may take several months.</p>	<ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot, or cold. • Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady. • Tell your healthcare team at your next visit if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.
<p>Dry eye commonly occurs.</p>	<ul style="list-style-type: none"> • You may use moisturizing eye drops or artificial tears for dry eyes. • Tell your healthcare team if you have eye pain, excess tears, blurry vision, or sensitivity to light.
<p>Minor bleeding, such as nosebleeds, may sometimes occur.</p>	<ul style="list-style-type: none"> • Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat. • Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes. • After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes. • Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped. • Get emergency help if a nosebleed lasts longer than 20 minutes.
<p>Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores can be painful and may lead to an infection.</p>	<ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. • Try the ideas in <i>Food Ideas to Try with a Sore Mouth</i>.* • Tell your healthcare team at your next visit as your dose may need to be changed.

SIDE EFFECTS	MANAGEMENT
<p>Your white blood cells may decrease after your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your healthcare team immediately at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine.
<p>Your platelets may decrease after your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). • For minor pain, try acetaminophen (e.g., TYLENOL®) first, to a maximum of 4 g (4000 mg) per day, but occasional use of ibuprofen may be acceptable.
<p>Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* <p>Tell your healthcare team if you have diarrhea for more than 24 hours.</p>
<p>Constipation may sometimes occur.</p>	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try the ideas in <i>Food Choices to Manage Constipation</i>.*

SIDE EFFECTS	MANAGEMENT
<p>Muscle or joint pain may sometimes occur.</p>	<p>You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) occasionally for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.</p>
<p>Hand-foot skin reaction may sometimes occur during treatment. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain, or ulcers occur.</p>	<ul style="list-style-type: none"> • Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. • Avoid tight-fitting jewellery. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply a sunscreen with an SPF (sun protection factor) of at least 30. • Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) to hands and feet, liberally and often. <p>Tell your healthcare team at your next visit if you have any signs of hand-foot skin reaction as your dose may need to be changed.</p>
<p>You may sometimes have trouble sleeping.</p>	<ul style="list-style-type: none"> • Tell your healthcare team if you continue to have trouble sleeping. • This will return to normal when you stop taking enfortumab vedotin.
<p>Taste alteration may sometimes occur.</p>	<p>Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i>.*</p>
<p>Loss of appetite and weight loss may sometimes occur.</p>	<p>Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>.*</p>
<p>Tiredness and lack of energy often occur.</p>	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i>.*
<p>Hair loss sometimes occurs with enfortumab vedotin. Hair will grow back once you stop treatment. Colour and texture may change.</p>	<p>If hair loss is a problem, refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</i>.*</p>

