Medication Information Sheet

enfortumab vedotin (en-FORT-ue-mab-ve-DOE-tin)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Padcev®

Appearance: colourless to light yellow liquid, mixed into larger bags of fluids

What is this medication for?

• For treating a certain type of bladder cancer

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- liver or eye problems,
- diabetes or high blood sugar,
- numbness or tingling in your hands or feet, or
- any allergies.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and Cancer Medications</u> pamphlet for more information.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance you may become pregnant, you and your partner together must use **2 effective forms of birth control** at the same time until at least **6 months** after your last dose. Talk to your health care team about which birth control options are best for you.
- If you are a patient that can get somebody pregnant, you and your partner together must use **2 effective forms of birth control** at the same time until at least **4 months** after your last dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and for at least 6 months after your last dose.

How is this medication given?

- This drug is given through an IV (injected into a vein). Talk to your health care team about your treatment schedule.
- If you missed your treatment appointment, talk to your health care team to find out what to do.

To Prevent or Treat Nausea and Vomiting

You may be given medications to prevent or stop nausea (feeling like throwing up) and vomiting (throwing up) before they start. These are called anti-nausea medications.

• Medications to prevent nausea and vomiting before they start include ondansetron (Zofran®), granisetron (Kytril®), or others.

If you already have nausea and/or vomiting, some anti-nausea medication can stop them from getting worse. You may be given these medications to have at home in case you start to feel nausea or if you vomit.

 Medications to stop nausea and vomiting include prochlorperazine (Stemetil®), metoclopramide (Maxeran®), or others.

What else do I need to know while on this medication?

Will this medication interact with other medications or natural health products?

- This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
- Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.

What should I do if I feel unwell, have pain, a headache or a fever?

- Always check your temperature to see if you have a fever before taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.
- Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- Talk to your health care team before you start taking Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take low dose aspirin for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO tell your health care team if you have any new pain, numbness or tingling of your hands or feet. This is especially important if you are having trouble doing tasks (like doing up buttons, writing, walking) or if you have severe pain or numbness.
- DO test your blood sugar regularly if you are taking any medications for diabetes. This treatment
 may cause changes in your blood sugar levels.

What NOT to DO while on this medication:

• DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.

What are the side effects of this medication?

The following table lists side effects that you may have when getting enfortumab vedotin. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on enfortumab vedotin.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Rash; dry, itchy skin	Talk to your health care team if it
(May be severe)	does not improve or if it is severe.
What to look for?	or it it is severe.
 You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. 	
What to do?	
To prevent and treat dry skin:	
 Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. 	
Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.	
Fatigue	Talk to your health
What to look for?	care team if it does not improve
 Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. 	or if it is severe.
What to do?	
 Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Ask family or friends to help you with things like housework, shopping, and child or pet care. 	

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
 Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. Ask your health care team for the <u>Fatigue</u> pamphlet for more information. 	
 Neuropathy (Tingling, numb toes or fingers) (May be severe) What to look for? Numbness or tingling of your fingers and toes may happen after starting your treatment. It can also happen to other parts of your body. Sometimes it can be painful and feel like a burning sensation, which may be severe. 	Talk to your health care team, especially if you have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain or numbness.
 What to do? Talk to your health care team if you have symptoms of neuropathy. Numbness and tingling may slowly get better after your treatment ends. In rare cases, it may continue long after treatment ends. If you continue to have bothersome symptoms, talk to your health care team for advice. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Hair thinning or loss What to look for?	Talk to your health care team if this bothers you.
 Your hair may become thin or fall out during or after treatment. In most cases, your hair will grow back after treatment. The texture or colour may change. In very rare cases, hair loss may be permanent. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
Use a gentle soft brush.Do not use hair sprays, bleaches, dyes and perms.	
Low appetite	Talk to your health
What to look for?	care team if it does not improve
Loss of interest in food or not feeling hungry.Weight loss.	or if it is severe.
What to do?	
 Try to eat your favourite foods. Eat small meals throughout the day. You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have no appetite. 	
Ask your health care team for the <u>Loss of Appetite</u> pamphlet for more information.	
Diarrhea	Talk to your health
What to look for?	care team if no improvement after 24 hours of taking
 Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. 	diarrhea medication or if severe (more than 7 times in one
What to do?	day).
If you have diarrhea:	
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol, until your diarrhea has stopped. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. 	
Ask your health care team for the <u>Diarrhea</u> pamphlet for more information.	
Nausea and vomiting	Talk to your healthcare team if
(Generally mild)	nausea lasts more than 48 hours or
What to look for?	vomiting lasts more than 24
 Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. 	hours or if it is severe.
What to do?	
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (like coffee, tea) and avoid alcohol. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the Nausea & Vomiting pamphlet for more information. Talk to your health care team if: 	
nausea lasts more than 48 hoursvomiting lasts more than 24 hours or if it is severe	
Constipation	Talk to your health
What to look for?	care team if it does not improve or if it is severe.
 Having bowel movements (going poo) less often than normal. Small hard stools (poo) that look like pellets. The need to push hard and strain to have any stool (poo) come out. 	5. 11 10 00 00 00 00

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 Stomach ache or cramps. A bloated belly, feeling of fullness, or discomfort. Leaking of watery stools (poo). Lots of gas or burping. Nausea or vomiting. 	
What to do?	
To help prevent constipation:	
 Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. Be Active. Exercise can help to keep you regular. If you take opioid pain medication, ask your health care team if eating more fibre is right for you. 	
To help treat constipation:	
 If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. 	
Ask your health care team for the Constipation Pamphlet for more information.	
Taste changes	Talk to your health
What to look for?	care team if it does not improve
Food and drinks may taste different than usual.	or if it is severe.
What to do?	
 Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables. Taste foods at different temperatures, since the flavour may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Mild joint, muscle pain or cramps What to look for?	Talk to your health care team if it does not improve or if it is severe.
New pain in your muscles or joints, muscle cramps, or feeling achy. What to do?	
What to do?	
 Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), 	
 ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. Rest often and try light exercise (such as walking) as it may help. 	
Ask your health care team for the Pain pamphlet for more information.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Dry eyes; eye problems	Talk to your health care team as soon
(May be severe)	as possible.
What to look for?	
 Your eyes may feel dry, irritated, or painful. They may look red and have a lot of tears. They may feel sensitive to light and your vision may be blurry. 	
What to do?	
 Avoid wearing contact lenses. Wear sunglasses with UV protection. Use protective eyewear (goggles or helmet with face mask) when playing sports, mowing the lawn or doing anything that may get particles or fumes in your eyes. 	
 You may try artificial tears (eye drops) or ointment. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Liver problems Your health care team may check your liver function with a blood test. Liver changes do not usually cause any symptoms.	Get emergency medical help right away.
What to look for?	
Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly.	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	
Low neutrophils (white blood cells) in the blood (neutropenia) (May be severe) When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information. What to look for? If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol® (acetaminophen), or Advil® (ibuprofen)). Do not eat or drink anything hot or cold right before taking your temperature.	If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you MUST get emergency medical help right away.
You have a fever if your temperature taken in your mouth (oral temperature) is: • 38.3°C (100.9°F) or higher at any time OR	
• 38.0°C (100.4°F) or higher for at least one hour.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
If your health care team has told you that you have low neutrophils:	
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	
Low platelets in the blood	Talk to your health care team if you
When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the <u>Low Platelet Count</u> pamphlet for more information.	have any signs of bleeding. If you have bleeding that doesn't stop or is
What to look for?	severe (very
Watch for signs of bleeding:	heavy), you MUST get emergency
bleeding from your gums	help right away.
unusual or heavy nosebleedsbruising easily or more than normal	
 black coloured stools (poo) or blood in your stools (poo) 	
coughing up red or brown coloured mucusdizziness, constant headache or changes in your vision	
 heavy vaginal bleeding 	
 red or pink coloured urine (pee) 	
What to do?	
If your health care team has told you that you have low platelets:	
 Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. Check with your healthcare team before you go to the dentist. Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 Ask your health care team what activities are safe for you. Your treatment may have to be delayed if you have low platelets. Your health care team may recommend a blood transfusion. 	
If you have signs of bleeding:	
 If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes. 	
If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.	
High blood sugar (May be severe)	Talk your health care team as soon as possible.
What to look for?	as possible.
 You may feel thirsty. You may pee more often than usual. You may feel tired or sleepy. 	
What to do?	
 Your health care team may do a blood test to check your blood sugar level. You may be told to change your diet or given medication to lower your blood sugar. If you have diabetes, check your blood sugar regularly. Your health care team may ask you to check it more often than usual. 	
Trouble Sleeping	Talk to your health
Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.	care team if it does not improve or if it is severe.
What to look for?	
 You may find it hard to fall asleep or stay asleep. How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep. You may wake up too early or not feel well-rested after a night's sleep. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
You may feel tired or sleepy during the day.	
What to do?	
Talk to your health care team if it does not improve or if it is severe.	

Other rare, but serious side effects are possible. If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- an irregular or fast heartbeat
- cough, breathing problems, or cough up blood
- pain, redness, swelling or tenderness where your medication was given
- tingling or swelling of the skin on the palms of your hands and the bottoms of your feet

Who do I contact if I have questions or need help?
My cancer health care provider is:
During the day I should contact:
Evenings, weekends and holidays:
Other Notes:

enfortumab vedotin
March 2024 Updated "How will this medication affect sex, pregnancy and breastfeeding?" section
For more links on how to manage your symptoms go to <u>www.cancercareontario.ca/symptoms</u> .
The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.
A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.