

PADCEV™

(Enfortumab Vedotin)

Your Treatment Guide


What is PADCEV (Padcev™ Enfortumab Vedotin)?

PADCEV (Enfortumab Vedotin) is a medicine used for the treatment of adult patients with a type of bladder cancer called urothelial carcinoma that has spread or cannot be surgically removed (locally advanced or metastatic setting) who:

- Have previously received a PD-1 medicine or PD-L1 inhibitor combined with platinum-containing chemotherapy.
- Cannot be treated with Cisplatin-containing chemotherapy and have been previously treated with one or more treatment lines before starting PADCEV treatment¹.

The purpose of this guide is to provide a brief overview of your treatment. If you have questions or would like to receive more detailed information, please contact with your attending physician. The information in this brochure does not constitute a treatment recommendation. Always follow the instructions provided to you by your attending physician.

PADCEV 20 mg, Enfortumab Vedotin 20mg per vial
PADCEV 30 mg, Enfortumab Vedotin 30mg per vial¹



PADCEV™
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

What's inside

Since your attending physician has prescribed you PADCEV (Enfortumab Vedotin), the purpose of this brochure is to provide you with useful information about your medicine. Here you will receive an explanation about how this medicine works and what you need to know when taking it.

You may find it more beneficial to read this brochure together with your attending physician, who can better explain to you why this medicine was chosen as the most suitable treatment for you.

Your attending physician could also explain potential side effects that may present during the treatment and how to deal with them.

Before you start taking PADCEV (Enfortumab Vedotin), talk to your physician about all your medical issues and any other medicine you are taking, including prescription and off-counter medicines, vitamins, and herbal supplements.

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Facts about Bladder Cancer

Bladder Cancer (Urethral Carcinoma) is a type of cancer that begins at the layer that lines the urinary system organs – mainly the bladder, which is the organ that stores urine².

Bladder Cancer starts when the genes undergo specific changes, also called mutations, that cause the bladder cells to abnormally increase in size².

Locally advanced bladder cancer

a condition in which the cancer cells have spread to nearby areas

Metastatic urethral cancer

a condition in which the cancer cells have migrated to other regions of the body, such as lymph nodes or other organs



Chemotherapy: a treatment that uses medicines to stop the growth of cancer cells by killing those cells or preventing them from dividing. These medicines can affect cancer cells and healthy cells³.

Gene: a piece of DNA (the genetic material in humans) that parents pass on to their children. The genes contain instructions for making proteins, which are the building blocks of everything inside the body. Each individual has thousands of genes³.

Immunotherapy: a treatment that uses substances to provoke or suppress the immune system in order to help the body fight cancer, infection, and other diseases³.

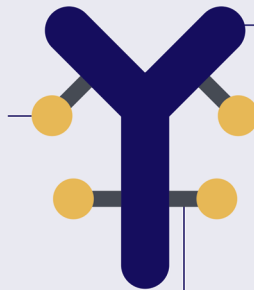
This brochure does not replace the instructions given to you by your physician. It is important to always talk to your physician if you have any questions about bladder cancer and/or your PADCEV (Enfortumab Vedotin) treatment.

What is PADCEV (Enfortumab Vedotin), and how does it work?

PADCEV (Enfortumab Vedotin) works differently than the chemotherapy or immunotherapy you were prescribed in the past since it is an antibody-drug conjugate (ADC)¹.

PADCEV (Enfortumab Vedotin) is made of 3 parts:¹

Cell-killing medicine (**medicine**) that is released inside the cell



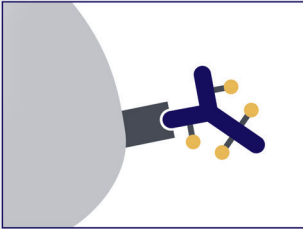
An **antibody** that attaches to a certain type of protein on the surface of a cell

A link that connects the cell-killing medicine to the antibody, creating a **conjugate**

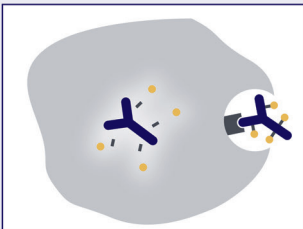


Antibody: a protein that is normally made by the body's immune system. The antibody that makes PADCEV (Enfortumab Vedotin) is manufactured in a lab³

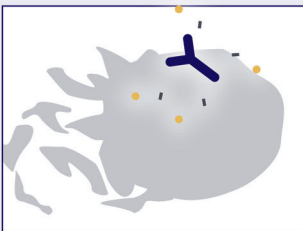
How does PADCEV (Enfortumab Vedotin) work:¹



1. The medicine attaches to the surface of the cancer cell



2. The medicine enters the cancer cell and releases the cell-killing medicine



3. This medicine may help to damage and kill the cancer cell

This is how PADCEV (Enfortumab Vedotin) was shown to work in laboratory studies

PADCEV (Enfortumab Vedotin) works by inserting the cell-killing medicine directly into the cancer cells, but it can also affect healthy cells and cause side effects. Talk to your attending physician about the side effects and see pages 8 and 9 for more information about this medicine's side effects.

How is PADCEV (Enfortumab Vedotin) administered?

- You will receive PADCEV (Enfortumab Vedotin) over periods of time called cycles. Each cycle is 28 days, and in each cycle, you are given 3 IV infusions¹
- Your attending physician will decide how many treatment cycles you need. Always take PADCEV (Enfortumab Vedotin) exactly as your attending physician instructs you¹
- Your attending physician may also do tests on a regular basis during treatment with PADCEV (Enfortumab Vedotin)¹

PADCEV (Enfortumab Vedotin) is given in an **intravenous infusion (IV)** for 30 minutes each week for 3 weeks, followed by a week of rest¹

The below timeline is only a visual representation of the medicine's schedule. It is not meant to be used to track your treatment cycle. Specific days of the week may vary based on your attending physician's recommendation.

		Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1	 30 min						
Week 2	 30 min						
Week 3	 30 min						
Week 4	One week in every cycle is dose-free						

During the treatment:

- You must make sure to keep your appointments and stay on schedule
- Talk to your attending physician about any problem you have scheduling meeting dates
- Talk to your attending physician if you feel unwell
- If you experience certain side effects, your attending physician may decrease your dose or stop your treatment with PADCEV (Enfortumab Vedotin) for a period of time until your symptoms either improve or are completely resolved⁴



Intravenous infusion (IV): administration method of a medicine or other substances through a needle or a tube inserted into the vein³

What are some of PADCEV's side effects?

Much like all medicines, PADCEV (Enfortumab Vedotin) may cause side effects, although not everyone experiences them. Please note that the below are just some of the side effects of PADCEV (Enfortumab Vedotin). You may experience other side effects while taking this medicine.

Some of the potential side effects might be serious:¹



Skin reactions (about 50% of the patients)

Signs and symptoms: rash or itching that continues to get worse or comes back after the treatment, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat or genital area, fever, or flu-like symptoms, or swollen lymph nodes



High blood sugar or hyperglycemia (may affect 1 in 10 people)

Signs and symptoms: frequent urination, increased thirst, blurred vision, confusion, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting, or stomach pain.



Lung tissue inflammation

Signs and symptoms: dry cough and shortness of breath



Nerve problems or peripheral neuropathy

(may affect up to 1 in 100 people)

Signs and symptoms: numbness, tingling, or a tingling sensation in your hands and feet, or muscle weakness



Vision Problems

Signs and symptoms: dry eyes or, alternatively, watery eyes, corneal inflammation, or blurred vision.



Leakage of PADCEV out of the vein into the tissues around the IV site (may affect up to 1 in 100 people)

Signs and symptoms: redness, swelling, itching, or discomfort at the IV site. If PADCEV leaks from the IV site or the vein into the nearby skin and tissues, it could cause a reaction in the IV site. These reactions might happen immediately after receiving the IV, but they often happen days after the IV.



Pregnancy

PADCEV may harm the fetus when administered to a pregnant woman. If you are a woman or man in your reproductive years, please get in touch with your physician for instructions¹



Get in touch with your physician immediately if you experience any of the above-listed symptoms during treatment with PADCEV (Enfortumab Vedotin)

Other potential side effects:¹

Below is a list of other potential side effects of PADCEV. Please talk to your attending physician if you experience any of the following symptoms.

Very common (may affect over 1 in 10 people):



Decreased red blood cells (anemia)

the symptoms include: feeling tired or cold, shortness of breath, dizziness, and weakness⁴



Nausea, diarrhea, and vomiting



Tiredness



Loss of appetite



Bad taste



Dry eyes



Hair loss



Weight loss



Elevated liver enzymes

(aspartate aminotransferase [AST] or alanine aminotransferase [ALT])
The symptoms include: nausea and vomiting, loss of appetite, frequent itching, and fatigue^{5,6}

Common (may affect over 1 in 100 people):



Abnormal walking

(as part of peripheral neuropathy symptom)
walking problems

For the full list of side effects, please see the physician's brochure



If you experience any side effects, talk to your attending physician.

This includes all potential side effects not listed in this guide.

If you are experiencing side effects that are not mentioned in this booklet, please consult with your attending physician.

You can report side effects to the Ministry of Health by clicking the link "report side effects following medicinal treatment," which refers you to the online form (www.health.gov.il) at the Ministry of Health's homepage to report a side effect, or by entering the link: <http://sideeffects.health.gov.il>

Make the most out of your medical appointments

It is important to trust your attending physician, but do not forget that you have an important role in your treatment. Browse the below advice to create an active partnership with your attending physician. It could help you make the most out of your treatment plan.



Ask questions

Your attending physician wants you to ask questions. It sometimes helps to make a list. If something your attending physician tells you is unclear, ask him to explain it to you again.



Monitor symptoms and side effects

Your daily feeling during the treatment may change. Use the log to keep track of how you feel every day. You can also use the monitoring log on page 7 to write any helpful reminders or potential side effects. Remember to talk to your attending physician about any side effect you experience or if any side effect has worsened.



Ask for help

Often the treatment may be difficult. Do not be afraid to turn to friends or family. Allow yourself to ask for help when you need it.



Talk to someone

Talk to someone, whether your attending physician or someone close to you, about what you have been going through. Talking to others is always a good way to keep yourself motivated!

This information brochure is provided as information to patients sponsored by Astellas Pharma International B.V

This guide is for people with bladder cancer (Urethral Carcinoma) that has spread or cannot be surgically removed, who had received an immunotherapy medicine with or without a platinum-containing chemotherapy medicine, and who received a prescription for PADCEV (Enfortumab Vedotin). Its purpose is to provide a short review. If you have any more questions, please talk to your attending physician.

Sources: 1. PADCEV™. PRODUCT INFORMATION AS APPROVED BY MOH. 2. Mayo Clinic. Bladder cancer. Available at: <https://www.mayoclinic.org/diseases-conditions/bladder-cancer/symptoms-causes/syc-20356104> [Accessed September 2021]. 3. National Cancer Institute. NCI Dictionary of Cancer Terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms> [Accessed September 2021]. 4. Mayo Clinic. Anemia. Available at: <https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360> [Accessed September 2021]. 5. Cleveland Clinic. Elevated Liver Enzymes. Available at: <https://my.clevelandclinic.org/health/symptoms/17679-elevated-liver-enzymes> [Accessed September 2021]. 6. Digestive Care Physicians, LLC. Available at: <https://digestivecarephysicians.com/abnormal-liver-enzymes/>[Accessed September 2021].

Reporting side effects

You can report side effects to the Ministry of Health by pressing the link report side effects following medicinal treatment on the Ministry of Health homepage:

<http://www.health.gov.il>

that refers to the online form to report side effects or by entering the link:

<http://sideeffects.health.gov.il>

The information is true for March 2022

For more information, contact the attending physician

Version 01: the template and content of this Patient's Brochure have been updated and approved by the Ministry of Health in 12.2022.



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