

Patient Booklet

PADCEV (enfortumab vedotin)

Your Treatment Guide

This guide provides important information about advanced bladder cancer and Padcev as part of your treatment. Since your doctor has prescribed Padcev (enfortumab vedotin), this brochure aims to give you helpful details about your medication. If you have questions or need more information, please reach out to your doctor.

The information here is not a treatment recommendation, always follow your doctor's instructions. It may be helpful to read this brochure with your doctor, who can explain why this medicine was prescribed for you and discuss any potential side effects and how to manage them. Before starting Padcev, talk to your doctor about your medical history and any other medications you are taking, including over-the-counter drugs, vitamins, and herbal supplements. This brochure does not replace your doctor's instructions, so always consult your doctor if you have questions about bladder cancer or your Padcev treatment.

WHAT IS PADCEV?

PADCEV is a prescription medicine PADCEV™, in combination with pembrolizumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer (mUC).

PADCEV, as a single agent, is indicated for the treatment of adult patients with locally advanced or mUC who:

- have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting, or
- are ineligible for cisplatin-containing chemotherapy and have previously received a PD-1/PD-L1 inhibitor.

It is not known if PADCEV is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PADCEV?

PADCEV may cause serious side effects, including:

Skin reactions. Skin reactions including severe skin reactions have happened in people treated with PADCEV and may be more common when PADCEV is given with pembrolizumab. In some cases, these severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:

- 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, nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

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

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

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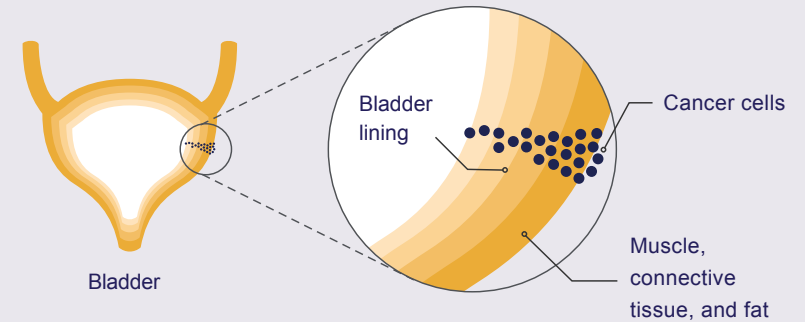
About advanced bladder cancer

What are advanced bladder cancer and cancers of the urinary tract?

Urothelial (bladder) cancer begins in the cells lining the organs (bladder, ureters, renal pelvis, and urethra) in the urinary system. When the cancer spreads to nearby areas, it is called **locally advanced cancer**. If it has spread to distant parts of the body, like the lymph nodes or other organs, it is called **metastatic cancer**.

Bladder cancer that has spread or cannot be removed with surgery is known as **advanced bladder cancer**.

How cancer spreads through the bladder



Who is PADCEV™ for?

PADCEV can be used by itself or together with pembrolizumab to treat advanced bladder cancer

Whether your doctor prescribes PADCEV alone or in combination with pembrolizumab depends on your bladder cancer treatment history.

What is PADCEV™?

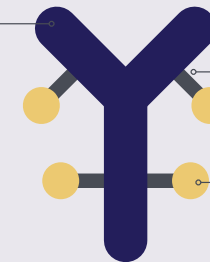
PADCEV is used to treat advanced bladder cancer

It is a type of prescription medicine known as an antibody-drug conjugate, or ADC.

- PADCEV is different from the chemotherapy or immunotherapy you may have had before
- PADCEV is thought to work by delivering cell-killing medicine directly to certain cancer cells.* However, it can also affect normal cells and cause side effects
- Talk to your healthcare professional about side effects, and see [pages 9-11](#) for information about possible side effects with PADCEV

PADCEV is made of 3 parts:

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

Cell-killing medicine that is released inside of the cell

*This is how PADCEV was shown to work in lab studies.

 **Antibody:** A protein most commonly made by the body's immune system. The antibody that makes up PADCEV is produced in a laboratory.

How PADCEV™ is thought to work

PADCEV is thought to target certain cancer cells with cell-killing medicine



This is how PADCEV was shown to work in lab studies.

PADCEV with pembrolizumab

Combines 2 therapies that treat advanced bladder cancer in different ways

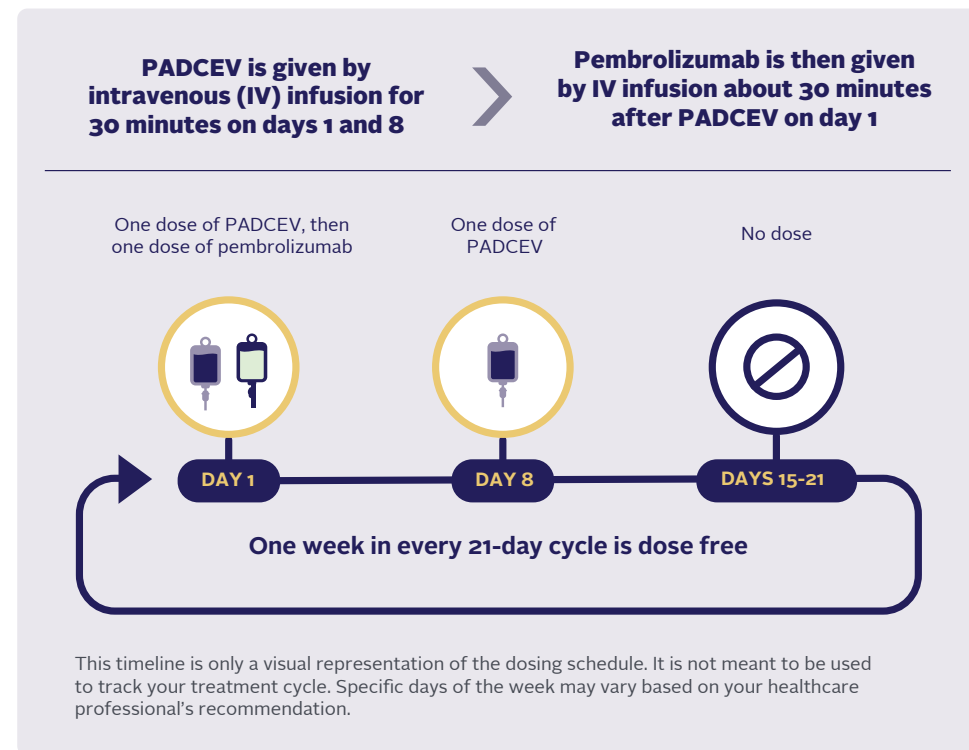


Please see the pembrolizumab patient medication guide for important safety information.

How is PADCEV™ + pembrolizumab given?

Each PADCEV + pembrolizumab treatment cycle is 21 days

Your healthcare professional will decide how many treatment cycles you need, and may do blood tests regularly during treatment.



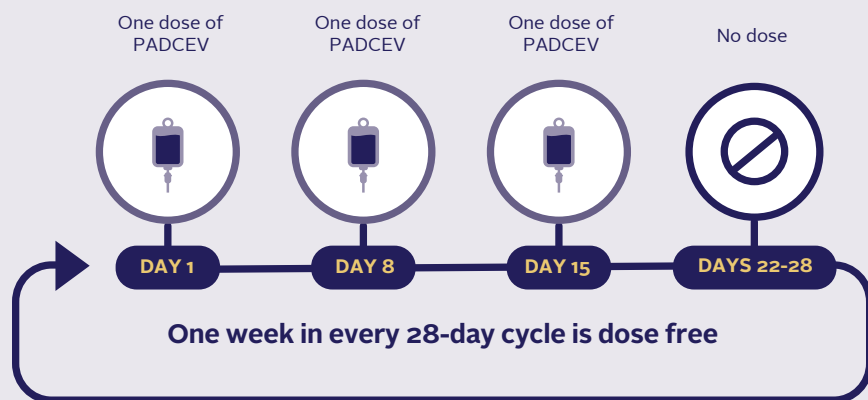
Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV due to side effects. It is important to play an active role and report side effects as soon as you experience them.

How is PADCEV™ alone given?

When given alone, each PADCEV treatment cycle is 28 days

Your healthcare professional will decide how many treatment cycles you need, and may do blood tests regularly during treatment.

PADCEV is given by IV infusion for 30 minutes on days 1, 8, and 15 of a 28-day treatment cycle



This timeline is only a visual representation of the dosing schedule. It is not meant to be used to track your treatment cycle. Specific days of the week may vary based on your healthcare professional's recommendation.



Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV due to side effects. It is important to play an active role and report side effects as soon as you experience them.

Important Safety Information

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PADCEV™?
PADCEV may cause serious side effects, including:



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- 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, nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes



Before receiving PADCEV, tell your healthcare provider about all of your medical conditions, including if you:

- Are currently experiencing numbness or tingling in your hands or feet.
- Have a history of high blood sugar or diabetes.
- Have liver problems.
- Are pregnant or plan to become pregnant. PADCEV can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with PADCEV.
- Are breastfeeding or plan to breastfeed. It is not known if PADCEV passes into your breast milk. Do not breastfeed during treatment and for 3 weeks after the last dose of PADCEV.



Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with PADCEV.
- You should use an effective method of birth control during your treatment and for at least 2 months after the last dose of PADCEV.



Males with a female sexual partner who is able to become pregnant:

- If your female partner is pregnant, PADCEV can harm the unborn baby.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of PADCEV.

Important Safety Information (cont'd)



Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PADCEV™ with certain other medicines may cause side effects.

What are the possible side effects of PADCEV?

PADCEV may cause serious side effects, including:

- **Skin Reactions.** See “What is the most important information I should know about PADCEV?”
- **High blood sugar (hyperglycemia).** An increase in blood sugar is common during treatment with PADCEV. Severe high blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have happened in people with and without diabetes treated with PADCEV. Tell your healthcare provider right away if you have any symptoms of high blood sugar, including: frequent urination, increased thirst, blurred vision, confusion, it becomes harder to control your blood sugar, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting, or stomach pain.
- **Lung problems.** PADCEV may cause severe or life-threatening inflammation of the lungs that can lead to death. These severe problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.
- **Nerve problems.** Nerve problems, called peripheral neuropathy, are common during treatment with PADCEV and can sometimes be severe. Nerve problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening numbness or tingling in your hands or feet or muscle weakness.
- **Eye problems.** Certain eye problems are common during treatment with PADCEV. Tell your healthcare provider right away if you have dry eyes, increased tearing, blurred vision, or any vision changes. You may use artificial tear substitutes to help prevent or treat dry eyes.
- **Leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation).** If PADCEV leaks from the injection site or the vein into the nearby skin and tissues, it could cause an infusion site reaction. These reactions can happen right after you receive an infusion, but sometimes may happen days after your infusion. Tell your healthcare provider or get medical help right away if you notice any redness, swelling, itching, blister, peeling skin or discomfort at the infusion site.

Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV if you have severe side effects.

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



Important Safety Information (cont'd)

If your healthcare provider prescribes PADCEV™ in combination with pembrolizumab for you, also read the Medication Guide that comes with pembrolizumab for important information about pembrolizumab.

The most common side effects of PADCEV when used in combination with pembrolizumab include:

- Changes in liver function and kidney function tests (a test done to check your pancreas)
- Rash. See “What is the most important information I should know about PADCEV?”
- Increased sugar (glucose) in the blood. See “High blood sugar (hyperglycemia)”
- Numbness or tingling in your hands or feet. See “Nerve problems”
- Increased lipase
- Decreased white blood cell, red blood cell, and platelet counts
- Tiredness
- Decreased sodium, phosphate, and protein (albumin) in the blood
- Itching
- Diarrhea
- Hair loss
- Decreased weight
- Decreased appetite
- Increased uric acid in the blood
- Increased or decreased potassium
- Dry eye. See “Eye problems”
- Nausea
- Constipation
- Change in sense of taste
- Urinary tract infection

The most common side effects of PADCEV when used alone include:

- Increased sugar (glucose) in the blood. See “High blood sugar (hyperglycemia)”
- Changes in liver and kidney function tests
- Decreased white blood cell, red blood cell, and platelet counts
- Rash. See “What is the most important information I should know about PADCEV?”
- Tiredness
- Numbness or tingling in your hands or feet. See “Nerve problems”
- Decreased protein (albumin), sodium, and phosphate in the blood
- Hair loss
- Decreased appetite
- Diarrhea
- Nausea
- Itching
- Increased uric acid in the blood
- Dry eye. See “Eye problems”
- Change in sense of taste
- Constipation
- Increased lipase (a blood test done to check your pancreas)
- Decreased weight
- Stomach (abdominal) pain
- Dry skin

PADCEV may cause fertility problems in females and males, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of PADCEV.



If you experience any side effects, talk to your attending physician. This includes all potential side effects not listed in this guide.

Adverse events reporting: Adverse events can be reported directly to the Ministry of Health using the adverse events digital form which available on the home page of the Ministry of Health website: www.health.gov.il or by this link: <https://sideeffects.health.gov.il/>

Adverse events may also be reported to Astellas Pharma International B.V using the following email: Pharmacovigilance.IL@astellas.com



Being your own healthcare advocate

Trusting your healthcare team is important, but don't forget that you play an important role in your care. Explore the tips below to build an active partnership with your healthcare team. These can help you get the most out of your treatment plan.



Ask questions

Your healthcare team wants you to ask questions. Sometimes it helps to keep a list. If you are unclear about something your healthcare professional says, ask them to explain it again.



Keep track of symptoms and side effects

Consider keeping a journal to keep track of any side effects you experience and how you are feeling each day.



Ask for help

Treatment may get difficult sometimes. Don't be afraid to reach out to friends and family.



Talk to someone

Talk to someone, whether a healthcare professional or a loved one, about what you're going through.



If you experience any side effects, talk to your attending physician. This includes all potential side effects not listed in this guide.

Adverse events reporting: Adverse events may also be reported directly to the Ministry of Health using the adverse events digital form which available on the home page of the Ministry of Health website: www.health.gov.il or by this link: <https://sideeffects.health.gov.il/>

Adverse events can also be reported to Astellas Pharma International B.V using the following email: Pharmacovigilance.IL@astellas.com





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Injection for IV infusion 20 mg & 30 mg vials