

PADCEV™ Discussion Guide and Symptom Tracker

This Discussion Guide and Symptom Tracker is designed to help you and your caregiver have more detailed conversations with your healthcare team. Use the symptom tracker to help you keep your healthcare team up to date on how you are feeling while taking PADCEV.

Office contacts:

Doctor: _____

Nurse: _____

Location: _____

Phone: _____

Appointment reminders:

Date: _____ Time: _____

WHAT IS PADCEV?

PADCEV (enfortumab vedotin-ejfv) is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. PADCEV may be used if you have received an immunotherapy medicine and also received a chemotherapy-containing platinum medicine. It is not known if PADCEV is safe and effective in children.

PADCEV was FDA-approved based on a clinical study that measured how many patients had a tumor response. There is another study with PADCEV to confirm the clinical benefit.

SELECT SAFETY INFORMATION

High Blood Sugar (hyperglycemia). You can develop high blood sugar during treatment 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.

Please see additional Important Safety Information on pages 5-6 and please visit [astellas.us/docs/PADCEV_label.pdf](https://www.astellas.us/docs/PADCEV_label.pdf) to see the full patient Prescribing Information.



Discussing PADCEV™ with your healthcare team

Starting a new treatment plan can raise questions. It is important for you and your caregiver(s) to talk to your healthcare team about all of the questions you have about treatment with PADCEV. This will help you get the most out of your treatment.

Below are some questions to help start a conversation about PADCEV

How is PADCEV different from other treatments I have tried?

How often will I receive PADCEV?

What are the possible side effects of PADCEV?

How will I know if PADCEV is working?



Bring this information to your next appointment to help you discuss any questions you have with your healthcare team.

Please see Important Safety Information on pages 5-6 and please visit astellas.us/docs/PADCEV_label.pdf to see the full patient Prescribing Information.



Tracking the symptoms you experience

During treatment with PADCEV, side effects can occur. You and your caregiver(s) should always talk to your doctor or nurse right away about any symptoms that you may experience.

Use the table below to track any symptoms you might be feeling while taking PADCEV. This may help your healthcare team manage your treatment.

For each day you experience a symptom, write the number that represents the degree of the symptom:



1

Hardly noticeable



2

Noticeable, but can still do usual activities



3

Uncomfortable, not able to do some activities



4

Very uncomfortable, hard to do any activities



5

Unbearable, not able to do any activities

List the symptoms that you are experiencing below	Week of:						
	S	M	T	W	T	F	S
Example: <i>Feeling tired</i>	1		2	2	3		1

NOTE: Print additional copies of this page to continue tracking your symptoms each week up until your next doctor appointment.

! Your healthcare provider may decrease your dose, temporarily stop, or completely stop giving PADCEV if you develop certain side effects during treatment with PADCEV.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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IMPORTANT SAFETY INFORMATION



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
- 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 at least 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.



Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



How will you receive PADCEV?

- PADCEV will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- You will receive your PADCEV over periods of time called cycles.
 - Each PADCEV cycle is 28 days.
 - You will receive PADCEV on days 1, 8 and 15 of every cycle.
- Your healthcare provider will decide how many treatment cycles you need.
- Your healthcare provider may do blood tests regularly during treatment with PADCEV.

Please see additional Important Safety Information on page 6 and please visit astellas.us/docs/PADCEV_label.pdf to see the full patient Prescribing Information.

 **PADCEV**[™]
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

What are the possible side effects of PADCEV?

PADCEV may cause serious side effects including:



- **High Blood Sugar (hyperglycemia).** You can develop high blood sugar during treatment 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.



- **Peripheral neuropathy.** While receiving PADCEV you may experience nerve problems called peripheral neuropathy. Tell your healthcare provider right away if you experience numbness or tingling in your hands or feet, or muscle weakness.



- **Eye problems.** You can develop certain eye problems while receiving PADCEV. Tell your healthcare provider right away if you have dry eyes or blurred vision.



- **Skin reactions.** Rashes and severe skin reactions can happen while receiving PADCEV. Tell your healthcare provider right away if you get a rash or a skin reaction that continues to get worse.



- **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, or discomfort at the infusion site.

The most common side effects of PADCEV include:

- numbness or tingling in your hands or feet, or muscle weakness
- fatigue
- decreased appetite
- rash
- hair loss
- nausea
- diarrhea
- change in sense of taste
- dry eyes
- dry skin

If you have certain side effects, your healthcare provider may decrease your dose or stop your treatment with PADCEV for a period of time (temporarily) or completely.

PADCEV may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of PADCEV.



Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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