

## PATIENT INFORMATION

PADCEV (PAD-sev)  
(enfortumab vedotin-ejfv)  
for injection

### What is PADCEV™?

PADCEV 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.

### 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.

#### 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.
- 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.

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

### How will I 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.

### 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 get 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 of the possible side effects of PADCEV.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of PADCEV.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about PADCEV, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about PADCEV that is written for healthcare professionals.

**What are the ingredients in PADCEV?**

**Active ingredient:** enfortumab vedotin

**Inactive ingredients:** histidine, histidine hydrochloride monohydrate, polysorbate 20, and trehalose dehydrate.

Manufactured and Marketed by: Astellas Pharma US, Inc., Northbrook, Illinois 60062

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For more information, go to [www.padcev.com](http://www.padcev.com) or call 1-888-4-PADCEV

This Patient Information has been approved by the U.S. Food and Drug Administration.

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