

PADCEV®

Patient Symptom Tracker

A guide to staying informed on potential side effects

You play an active role in your treatment journey. As you begin treatment with PADCEV alone or in combination with pembrolizumab (also known as Keytruda®), it is important to learn about potential side effects and pay close attention to any changes in your body.

Use this resource to keep track of potential side effects and to help guide conversations with your healthcare team.



It is important to immediately tell your healthcare team about any new or worsening symptoms or side effects. If you experience any new symptoms or if existing symptoms worsen, do not try to manage them on your own. Your healthcare team will work with you to treat them.

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 with pembrolizumab (also known as Keytruda®), **or**
- PADCEV may be used alone if you:
 - have received an immunotherapy medicine **and** chemotherapy that contains platinum, **or**
 - are not able to receive a chemotherapy that contains the medicine cisplatin **and** you have received 1 or more prior therapy.

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

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

See **“What are the possible side effects of PADCEV?”** for more information about side effects.

Please see Important Safety Information throughout and read the Patient Information for more information, including risk of **Serious Side Effects.**

 **PADCEV®**
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

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

See “What are the possible side effects of PADCEV?” for more information about side effects.



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.



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.






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Important Safety Information (cont'd)

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.

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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
- 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 (a test done to check your pancreas)
- 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.



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.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

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You play an active role during your treatment with PADCEV®

Discuss side effects with your healthcare team early and often

Side effects may occur at any time during treatment with PADCEV. Your healthcare team is there to help you during your treatment and relies on you to tell them about any new or worsening symptoms as soon as they occur. Your healthcare provider **may decrease your dose of PADCEV, or temporarily or completely stop your treatment** with PADCEV if you have side effects.

Dose modifications were common in the clinical trials of PADCEV and were an important way to treat side effects.

Each visit with your healthcare team is a chance for you to share how you are feeling



Tell your healthcare team exactly what your side effects are



Express how your side effects feel



Explain how long you have been experiencing your side effects



Show your healthcare team where your side effects are



Mention if the side effects change your daily routines

If you experience side effects, your healthcare team may recommend treatment strategies, such as dose modifications, additional medications, referral to specialists, lifestyle changes, or other therapies.

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Possible side effects

During treatment with PADCEV[®], either alone or in combination with pembrolizumab (also known as Keytruda[®]), you may experience certain side effects. **The diagrams on pages 6 and 7 show some of the most common and serious side effects experienced by patients taking PADCEV alone or in combination with pembrolizumab. If you experience any new or worsening symptoms, including the side effects and signs/symptoms shown below, please record them in the weekly symptom tracker (page 9) and share them with your healthcare team.**



Skin reactions

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



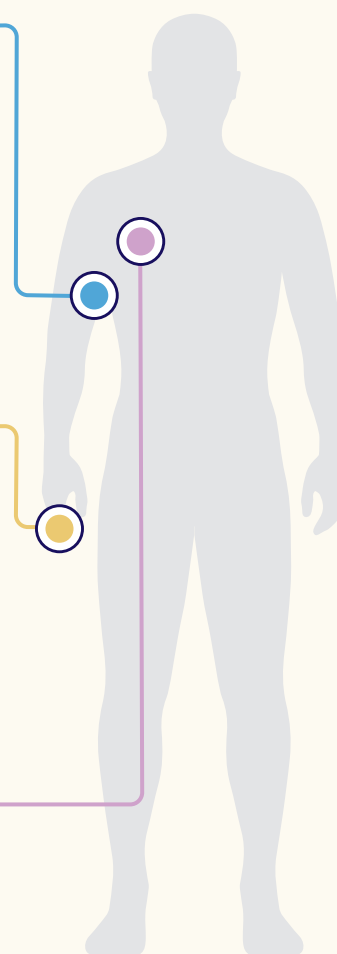
High blood sugar (hyperglycemia)

- 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

- Trouble breathing
- Shortness of breath
- Cough



Go to [page 7](#) for additional symptoms and side effects.

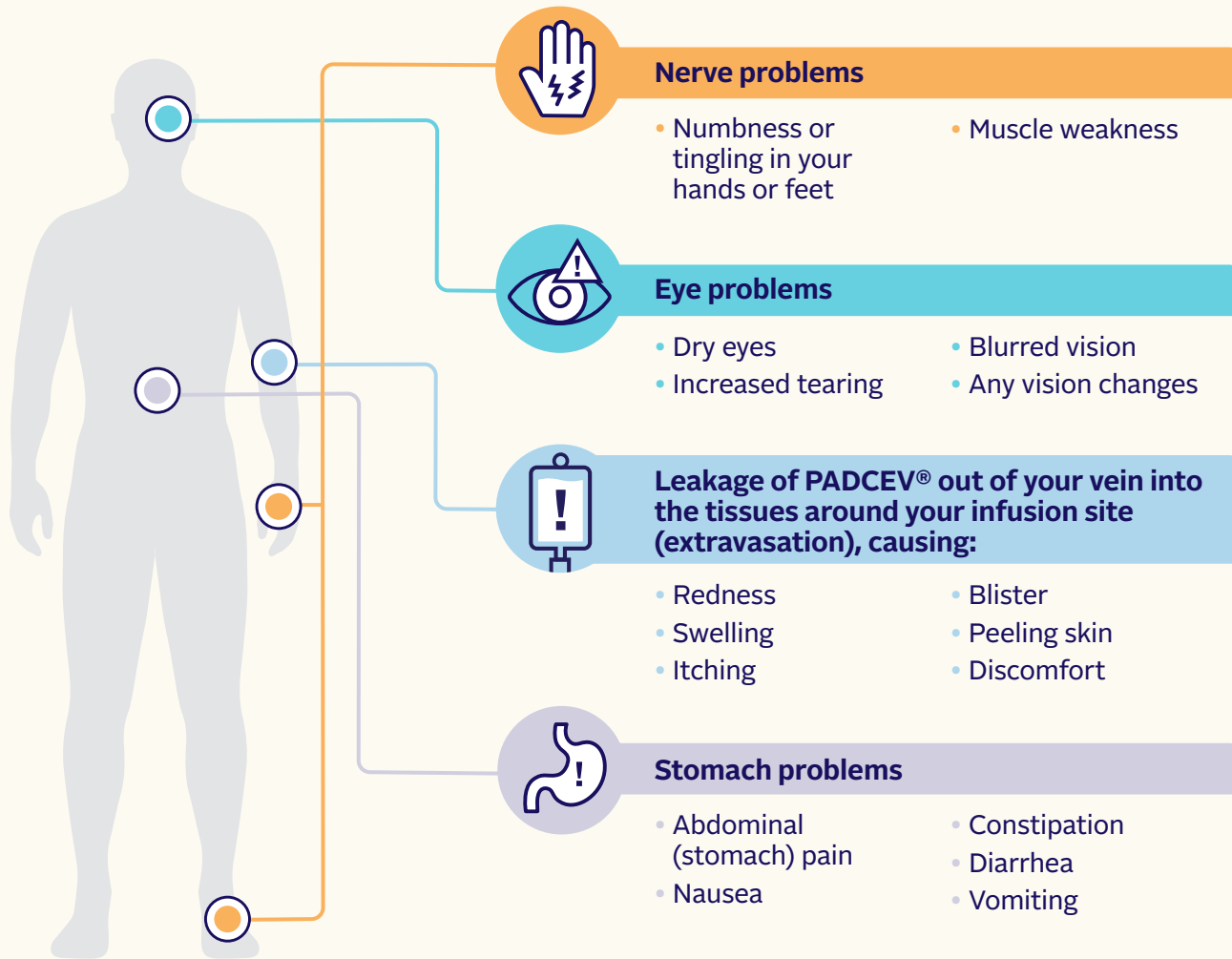
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Possible side effects (cont'd)



Please be aware that you may experience side effects or symptoms not listed on pages 6 and 7. It is important to immediately share any new or worsening side effects with your healthcare team. Do not try to manage side effects on your own. Your healthcare team will work with you to develop the best treatment plan for you.



Please be aware that you may experience additional side effects or symptoms not listed here. Reporting any and all side effects you experience will help your healthcare team develop the best treatment plan for you.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

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Tracking your symptoms

It is important to keep your healthcare team aware of how you are feeling. The earlier you let your healthcare team know about new or worsening symptoms, the more they may be able to help you. Use the table on the next page to track any symptoms and their severity you might experience during treatment.

Notes

Tracking your symptoms (cont'd)

For each day you experience a symptom, fill in the circle for the number that you think best represents the degree of the symptom.

 1 Hardly noticeable	 2 Noticeable, but can still do usual activities	 3 Uncomfortable, unable to do some activities	 4 Very uncomfortable, hard to do any activities	 5 Unbearable, unable to do any activities
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Week of: _____

List the symptoms that you are experiencing below		1	2	3	4	5
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[Click here](#) to download additional printable copies weekly to track and share any new or worsening symptoms with your healthcare team

For more information about PADCEV®,
please visit [PADCEV.com](https://www.padcev.com) or call
1-888-4PADCEV (1-888-472-3238)

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Visit [PADCEV.com/resources](https://www.padcev.com/resources) and find tools to help support you during treatment
with PADCEV



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