



Understanding Possible Side Effects With PADCEV®

A guide for patients taking PADCEV alone or with pembrolizumab

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 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.
- PADCEV may be used with pembrolizumab if you:
 - are not able to receive a chemotherapy that contains the medicine cisplatin.

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

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

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

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




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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 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 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. 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.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

-  **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.

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

- rash. **See “What is the most important information I should know about PADCEV?”**
- changes in liver and kidney function tests
- increased sugar (glucose) in the blood. **See “High blood sugar (hyperglycemia)”**
- tiredness
- decreased white blood cell, red blood cell, and platelet counts
- hair loss
- decreased appetite
- diarrhea
- decreased sodium, phosphate and protein (albumin) in the blood
- nausea
- itching
- change in sense of taste
- increased uric acid in the blood
- increased lipase (a blood test done to check your pancreas)
- decreased weight
- dry skin

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:

- increased sugar (glucose) in the blood. **See “High blood sugar (hyperglycemia)”**
- changes in liver function and kidney function tests
- rash. **See “What is the most important information I should know about PADCEV?”**
- decreased red blood cell and white blood cell counts
- tiredness
- decreased sodium, phosphate and protein (albumin) in the blood
- increased lipase (a test done to check your pancreas)
- hair loss
- decreased weight
- diarrhea
- itching
- decreased appetite
- nausea
- change in sense of taste
- urinary tract infection
- constipation
- increased or decreased potassium
- increased calcium in the blood
- swelling of the arms, hands, legs and feet
- dry eye. **See “Eye problems”**
- dizziness
- joint aches
- 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.

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About this guide

During treatment with PADCEV®, either alone or in combination with pembrolizumab, you may experience certain side effects. This guide is designed to help you recognize the symptoms of those side effects so you can promptly report them to your healthcare team.

Healthcare team contact information:

Name: _____ Phone/Email: _____

Name: _____ Phone/Email: _____

Name: _____ Phone/Email: _____

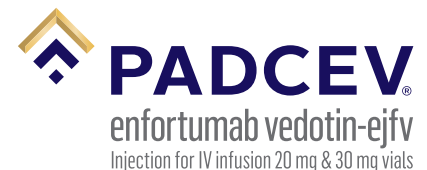
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Download the **PADCEV Discussion Guide and Symptom Tracker** to help keep track of your symptoms and guide conversations with your healthcare team.

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



What are some of the possible side effects of PADCEV®?

PADCEV may cause serious side effects, including: skin reactions, high blood sugar (hyperglycemia), lung problems, peripheral neuropathy, eye problems, and leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation).

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

- rash
- changes in liver and kidney function tests
- increased sugar (glucose) in the blood
- tiredness
- decreased white blood cell, red blood cell, and platelet counts
- hair loss
- decreased appetite
- diarrhea
- decreased sodium, phosphate and protein (albumin) in the blood
- nausea
- itching
- change in sense of taste
- increased uric acid in the blood
- increased lipase (a blood test done to check your pancreas)
- decreased weight
- dry skin

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

- increased sugar (glucose) in the blood
- changes in liver function and kidney function tests
- rash
- decreased red blood cell and white blood cell counts
- tiredness
- decreased sodium, phosphate and protein (albumin) in the blood
- increased lipase (a test done to check your pancreas)
- hair loss
- decreased weight
- diarrhea
- itching
- decreased appetite
- nausea
- change in sense of taste
- urinary tract infection
- constipation
- increased or decreased potassium
- increased calcium in the blood
- swelling of the arms, hands, legs and feet
- dry eye
- dizziness
- joint aches
- dry skin


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



It's important to immediately report any new or worsening side effects to your healthcare team.

Do not try to manage side effects on your own, your healthcare team will work with you to treat them.

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Skin reactions

Severe skin reactions have happened in people treated with PADCEV®, and may be more common when PADCEV is given with pembrolizumab. In some cases severe skin reactions have caused death.

Most common skin reactions seen in PADCEV clinical trials

- Rash
- Itching
- Hair loss
- Dry skin

Skin reactions occurred in 56% of the 753 people treated with PADCEV alone in clinical trials. Most severe skin reactions occurred during the first cycle of treatment but may happen later.

When PADCEV and pembrolizumab were given together, patients in clinical trials had skin reactions more often than when PADCEV was given alone. Skin reactions occurred in 72% of the 121 people treated with PADCEV and pembrolizumab together. More than half the time, severe skin reactions occurred around the third month of treatment.

Severe skin reactions may happen at any time during treatment, so tell your healthcare team if you're experiencing symptoms.

Tell your healthcare provider right away if you develop any of these signs of new or worsening 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

Notes:

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



If you are experiencing skin reactions



It's important to immediately report any new or worsening symptoms of skin reactions to your healthcare team. If you experience any symptoms of skin reactions, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.



Treatment modifications



Additional medication: _____



Referral to a dermatologist: _____



Avoiding hot baths/showers if experiencing itching



Covering skin with clothing/hats and using sunscreen



Using mild detergents and skin cleansers



Using alcohol-free, fragrance-free, hypoallergenic moisturizers



Using hypoallergenic makeup



Avoiding over-the-counter acne medications during and after cancer treatment

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If you are experiencing high blood sugar



It's important to immediately report any new or worsening symptoms of high blood sugar to your healthcare team. If you experience any symptoms of high blood sugar, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.



Treatment modifications



Additional medication: _____



Referral to a specialist: _____




Monitoring blood glucose readings at home



Additional suggestions from healthcare team: _____

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If you are experiencing lung problems



It's important to immediately report any new or worsening symptoms of lung problems to your healthcare team. If you experience any symptoms of lung problems, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.




Treatment modifications



Additional suggestions from healthcare team: _____

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Nerve problems (peripheral neuropathy)

Symptoms you may experience with nerve problems

- Pain/burning
- Numbness or tingling in hands or feet
- Loss of sensation
- Loss of coordination
- Muscle weakness
- The sense of wearing an invisible glove or sock over your hands or feet

Peripheral neuropathy may impact your ability to:

- Bathe/use the toilet
- Dress/button up your clothes
- Feed yourself/make meals
- Shop/handle money
- Take medications

Nerve problems called peripheral neuropathy occurred in 53% of the 753 people treated with PADCEV® alone in clinical trials, and more than half the time moderate or worse nerve problems occurred around the fifth month of treatment.

When PADCEV and pembrolizumab were given together, patients in clinical trials experienced nerve problems more often than when PADCEV was given alone. Nerve problems occurred in 65% of the 121 people treated with PADCEV and pembrolizumab. More than half the time, moderate or worse nerve problems occurred around the sixth month of treatment.

Nerve problems may occur at any time during treatment, so tell your healthcare team if you're experiencing any symptoms.

Notes:

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



If you are experiencing nerve problems



It's important to immediately report any new or worsening symptoms of nerve problems to your healthcare team. If you experience any symptoms of nerve problems, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.



Treatment modifications



Additional medication: _____



Referral to a specialist: _____



Referral for other therapy: _____

If you are experiencing nerve problems, talk with your healthcare team about making these daily life adjustments.



Wearing hard-soled slippers or shoes



Removing objects from walking areas, such as hallways



Using skid-free shower/bathroom mats



Using a cane or walker during treatment



Avoiding exposure of fingers and toes to very hot or very cold temperatures

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If you are experiencing eye problems



It's important to immediately report any new or worsening symptoms of eye problems to your healthcare team. If you experience any symptoms of eye problems, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.



Treatment modifications



Additional medication: _____



Referral to a specialist: _____

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If you are experiencing extravasation



It's important to immediately report a reaction after you receive an infusion to your healthcare team. If you experience leakage of PADCEV® out of your vein into the tissues around your infusion site, do not try to manage it on your own.

Prior to your infusion, talk with your healthcare team about the risk of experiencing leakage of PADCEV out of your vein into the tissues around your infusion site.



Additional suggestions from healthcare team: _____

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If you are experiencing gastrointestinal problems



It's important to immediately report any new or worsening symptoms of gastrointestinal problems (such as decreased appetite, nausea, diarrhea, or change in sense of taste) to your healthcare team. If you experience any symptoms of gastrointestinal problems, or existing symptoms worsen, do not try to manage them on your own.

Talk with your healthcare team about the following and ask them for their recommendations.



Treatment modifications



Additional medication: _____



Referral to a specialist: _____



Eating a "BRAT diet" (bananas, rice, applesauce, toast) and avoiding dairy and heavily spiced foods while experiencing diarrhea



Staying hydrated



Using lemon juice and chewing gum prior to meals



Having small frequent meals



Drinking water with meals



Practicing good oral hygiene



Using plastic instead of metal utensils




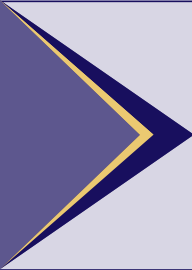
Using more/less salt and flavoring for food



Avoiding foods with strong smells

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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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