Muscle-Invasive Bladder Cancer (MIBC)*

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

Patient symptom tracker

A guide to staying informed on potential side effects

*Cancer that has spread into the muscle layer of the bladder but not to other parts of the body.

You can play an active role in your MIBC treatment journey. Use this resource to track your symptoms and how you are feeling, and share that information with your healthcare team.

During treatment with PADCEV® in combination with pembrolizumab (Keytruda®) or PADCEV in combination with pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™), given before and after surgery for MIBC, it is important to learn about potential side effects and pay close attention to any changes in your body.

WHAT IS PADCEV (enfortumab vedotin-ejfv)?

PADCEV is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra).

- PADCEV may be used with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph before and after the surgical removal of your bladder when your bladder cancer has spread into the muscle layer of the bladder (muscle invasive bladder cancer [MIBC]) but not to other parts of the body.

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 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.

Important Safety Information

IMPORTANT SAFETY INFORMATION

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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.

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, and death have happened in people with and without diabetes treated with PADCEV. Tell your healthcare provider right away if you get 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 Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

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Important Safety Information (cont'd)

- **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 get 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, blistering, 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 get severe side effects.

If your healthcare provider prescribes PADCEV in combination with the medicines pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, also read the Medication Guide that comes with each of these medicines for additional important information.

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

- Changes in liver function and kidney function tests
- Rash
- Increased sugar (glucose) in the blood
- Numbness or tingling in your hands or feet
- 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
- Nausea
- Constipation
- Change in sense of taste
- Urinary tract infection

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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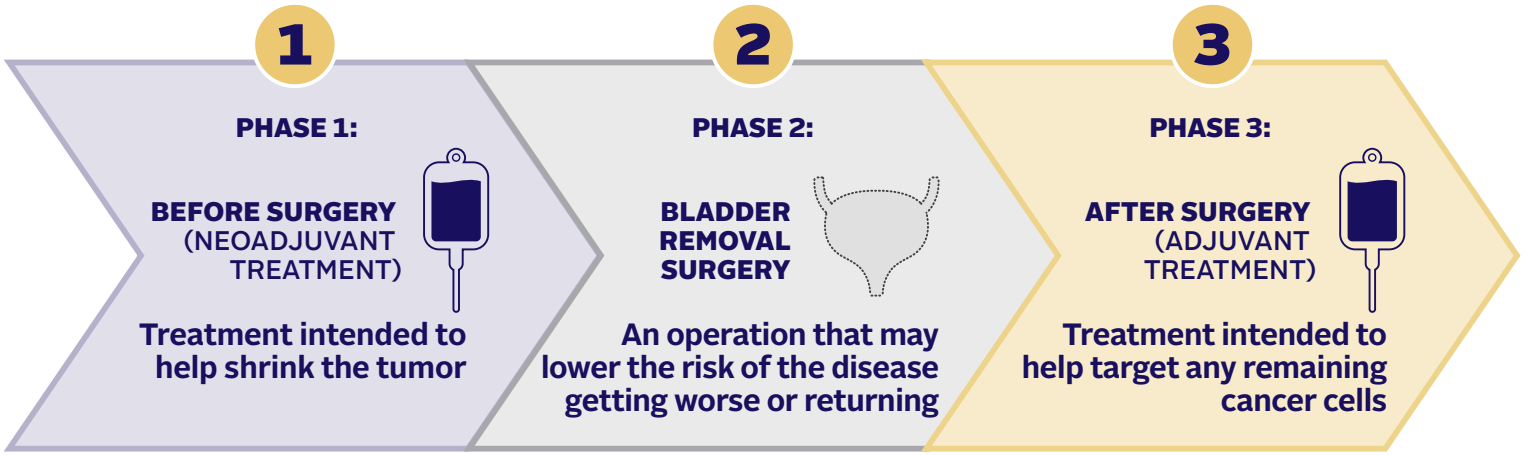
Understanding treatment before and after your surgery

TREATMENT IS GIVEN BEFORE AND AFTER SURGERY



- **Before surgery (neoadjuvant):**
  Treatment intended to help shrink the cancer
- **After surgery (adjuvant):**
  Even when the bladder is removed, cancer cells can still be present. The goal of adjuvant treatment is to help target those cells

Treatment with PADCEV® may also target healthy cells, which may result in side effects.

Make sure you are playing an active role throughout your treatment by promptly reporting any treatment-related side effects or surgery-related complications to your healthcare team.

Please see Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

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You can play an active role during your treatment with PADCEV® + pembrolizumab, given before and after surgery

Discuss side effects with your healthcare team early and often

Your healthcare team is there to help you during your treatment and relies on you to report any new or worsening side effects as soon as they happen. Please note that treatment-related side effects can occur at any point during treatment, so it is important to report any signs or symptoms early and often. Your healthcare provider **may decrease your dose of PADCEV or temporarily or completely stop your treatment** with PADCEV if you have side effects. If you experience side effects from treatment before bladder removal surgery, your doctor may still determine that you would benefit from treatment after surgery.

Dose modifications were common in the clinical studies of PADCEV and were an important way to help manage 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
- Describe how your side effects feel
- Show your healthcare team where your side effects are
- Explain how long you have been experiencing your side effects
- Mention if the side effects have changed your daily routines

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

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Possible side effects of PADCEV® in combination with pembrolizumab

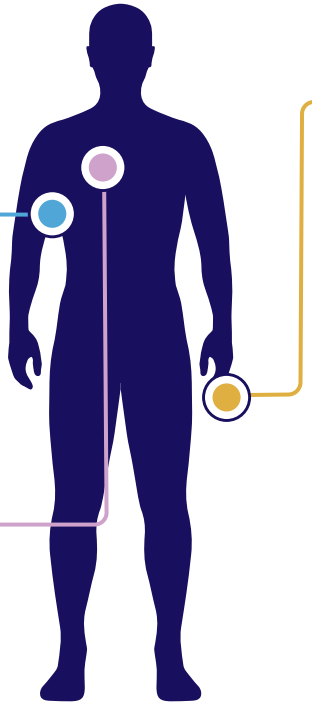
During treatment with PADCEV in combination with pembrolizumab (Keytruda®), given before and after surgery, you may experience side effects. Side effects may occur at any point during treatment. **The diagrams on pages 6 and 7 show some of the most serious side effects that may be commonly experienced by people receiving PADCEV in combination with pembrolizumab. If you experience any new or worsening symptoms, including the side effects shown below, you can 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

Lung problems

- Trouble breathing
- Shortness of breath
- Cough



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

Please be aware that you may experience additional side effects not listed here. Promptly reporting any and all side effects you experience will help your healthcare team develop an appropriate treatment plan for you.

Go to page 7 for additional symptoms and side effects.

Please see Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

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Possible side effects of PADCEV® in combination with pembrolizumab (cont'd)

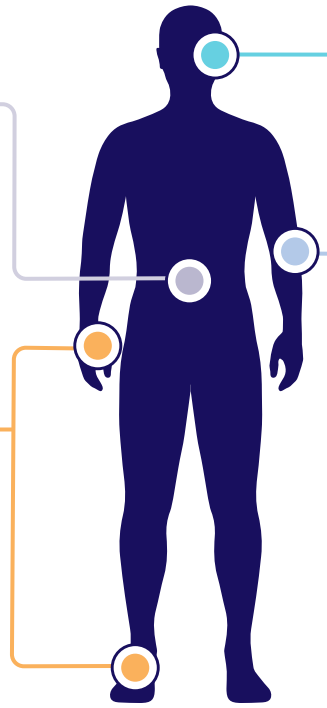
Please be aware that you may experience side effects not listed on pages 6 and 7. It is important to immediately share any new or worsening symptoms with your healthcare team. Do not try to manage side effects on your own. Your healthcare team will work with you to develop an appropriate treatment plan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

Stomach problems

- Decreased appetite
- Constipation
- Nausea
- Diarrhea

Nerve problems

- Numbness or tingling in your hands or feet
- Muscle weakness



Eye problems

- Dry eyes
- Increased tearing
- Blurred vision
- Any vision changes

Leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation), causing:

- Redness
- Swelling
- Itching
- Blister
- Peeling skin
- Discomfort

Please be aware that you may experience additional side effects not listed here. Promptly reporting any and all side effects you experience will help your healthcare team develop an appropriate treatment plan for you.

Please see Important Safety Information on pages 1-3 and read the Patient Information here 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 immediately. The sooner you let your healthcare team know about new or worsening symptoms, the more they may be able to help you. Use the table on **page 9** to track any symptoms you experience during treatment, along with their severity. You may also find it helpful to take photos of any changes in your symptoms to share with your healthcare team.

Notes

Please see Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

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Tracking your symptoms (cont'd)

Each day you experience a symptom, describe the symptom below and fill in the circle that represents how much it affected your day.

Week of: _____

	List the symptoms that you are experiencing below:	1 2 3 4 5
SUN		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
MON		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
TUE		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
WED		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
THU		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
FRI		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
SAT		○ ○ ○ ○ ○
		○ ○ ○ ○ ○
		○ ○ ○ ○ ○

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

Click here to download additional printable copies weekly to track and share any new or worsening symptoms with your healthcare team.

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For more information about PADCEV®, please visit PADCEV.com/mibc or call 1-888-4PADCEV (1-888-472-3238).

Please see Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

Visit PADCEV.com/mibc and find tools that can help support you during your treatment with PADCEV.

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Pfizer Oncology

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