

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PADCEV

enfortumab vedotin for injection

Read this carefully before you start taking **Padcev** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug.

Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Padcev**.

What is Padcev used for?

Padcev is a medicine used to treat adults with bladder cancer and cancer of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery.

- Padcev may be used with pembrolizumab or
- Padcev may be used alone if you have received chemotherapy that contains platinum and an immunotherapy medicine.

Serious Warnings and Precautions

- Skin reactions: Severe and fatal skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have occurred in patients treated with Padcev (see section *What are possible side effects from using Padcev?*)
- High blood sugar: High blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have occurred in patients with and without diabetes treated with Padcev (see section *What are possible side effects from using Padcev?*)

Padcev may be given in combination with pembrolizumab, read the Patient Medication Information for that product as well. If you have any questions about this medicine, please ask your doctor.

How does Padcev work?

Padcev contains enfortumab vedotin. Enfortumab vedotin has 2 parts. One part belongs to a group of medicines called monoclonal antibodies or mAbs. The other belongs to a group of medicines called anti-mitotics. This therapy kills the cancer cell once the antibody finds it.

What are the ingredients in Padcev?

Medicinal ingredients: enfortumab vedotin

Non-medicinal ingredients: histidine monohydrochloride monohydrate, polysorbate 20, trehalose dihydrate

Padcev comes in the following dosage forms:

Padcev comes in single-use vials containing 20 mg or 30 mg of enfortumab vedotin for injection.

Do not use Padcev if:

- You are allergic to enfortumab vedotin or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Padcev. Talk about any health conditions or problems you may have, including if you:

- have a history of high blood sugar or diabetes
- have any of the following skin problems, which could be the sign of a reaction:
 - rash or itching that continues to get worse or comes back after treatment
 - skin blistering or peeling
 - painful sores or ulcers in mouth or nose, throat, or skin around your penis or vagina
 - fever or flu-like symptoms or swollen lymph nodes
- are currently experiencing numbness or tingling in your hands or feet
- have eye problems such as very dry eyes and/or blurred vision
- have or have had liver problems
- have or have had kidney problems.

Other warnings you should know about:**Female Patients:**

- Padcev may harm your unborn baby and should not be used if you are pregnant.
- If you can get pregnant, your healthcare professional should do a pregnancy test before you start treatment with Padcev.
- You should use an effective birth control method during your treatment and for at least 6 months after stopping Padcev.
- It is not known if Padcev passes into your breast milk and could harm your baby. You should not breastfeed during treatment and for at least 6 months after stopping Padcev.

Male patients with female sexual partners who are pregnant, might be pregnant or could become pregnant:

- You should use an effective contraception during your treatment and for at least 4 months after stopping Padcev.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Padcev:

- Some medicines may change the amount of the Padcev in your body, such as ketoconazole (anti-fungal).

How to take Padcev:

- Padcev will be given to you by a healthcare professional in a healthcare setting.
- Padcev will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- If you receive Padcev with pembrolizumab, each cycle is 21 days. You will receive Padcev on days 1 and 8 of every cycle.
- If you receive Padcev alone, Padcev will be given to you over a period of 28 days. We call this a cycle. You will receive this medicine once a week for 3 weeks in every cycle. Then you will take a week off before starting the next cycle.
- Your healthcare professional will tell you how many treatment cycles you need.
- You may have blood tests during treatment with this medicine.

Usual dose:

The dose of Padcev depends on your body weight. The usual starting dose of this medicine is 1.25 mg for each kilogram of your body weight up to 100 kg. Your healthcare professional may need to pause, stop or lower your dose of this medicine. This can happen if you have certain side effects or if your disease gets worse.

Overdose:

It is unlikely that you will receive too much Padcev as you will be closely monitored by healthcare professionals during your infusion.

If you think you have taken too much Padcev contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your appointment to receive Padcev, you should make every effort to receive the missed dose as soon as possible. Doses should be given at least 1 week apart.

What are possible side effects from using Padcev?

These are not all the possible side effects you may have when taking Padcev, either alone or in combination with pembrolizumab. If you experience any side effects not listed here, tell your healthcare professional.

Very common

- low red blood cells (anemia)
- feeling sick to your stomach (nausea)
- watery poop (diarrhea)

- throwing up (vomiting)
- feeling tired
- not wanting to eat (decreased appetite)
- bad taste in your mouth
- rash
- hair loss
- weight loss
- high levels of enzymes called aspartate aminotransferase or alanine aminotransferase
- itching
- changes in liver & kidney tests for function
- increased uric acid in blood
- dry skin
- difficulty sleeping
- difficulty pooping (constipation)
- stomach pain
- fever
- urinary tract infection
- pain in the muscles and bones
- bleeding

Common

- low numbers of a type of white blood cell called neutrophils (neutropenia)
- low platelet counts
- increased lipase
- infection in the blood
- discoloration or abnormal darkening of the skin (skin hyperpigmentation, skin discoloration, pigmentation disorder)

Taking Padcev with pembrolizumab may cause additional possible side effects. These can include:

Very common

- Reduced thyroid gland activity (hypothyroidism)
- Swelling of lower legs or hands (edema peripheral)
- COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2)
- Cough
- Feeling out of breath (dyspnea)
- Low levels of calcium in your blood (hypocalcemia)

Common

- Problems with your liver (hepatitis) that can make your eyes and skin turn yellow
- High levels of a hormone made by your thyroid (hyperthyroidism)

- Low levels of hormones made by your adrenal glands (adrenal insufficiency)

Uncommon

- Inflammation of the muscles (myositis)
- Serious muscle weakness (myasthenia gravis)
- Very low white blood cells with a fever (febrile neutropenia)
- Damage to your heart muscle (myocarditis)
- Fast heartbeat while resting (tachycardia)
- Swollen pituitary gland (hypophysitis)
- High levels of sugar in your blood (diabetes mellitus)
- Swelling of the thyroid (thyroiditis)
- Swelling and redness in your eyes (uveitis)
- Swollen pancreas (pancreatitis)
- Liver problems caused by your immune system (immune-mediated hepatitis)
- Painful swelling in your gut (cholangitis sclerosing)
- Swelling caused by problems with your immune system (sarcoidosis)
- Blood infection (sepsis)
- Brain swelling caused by a problem with your immune system (immune-mediated encephalitis)
- Swelling of the kidneys caused by a problem with your immune system (immune-mediated nephritis)
- Allergic reaction (hypersensitivity)

If you take Padcev with pembrolizumab, read the Patient Medication Information for that product as well.

If you get any serious side effects with Padcev when used alone (single agent) or in combination with pembrolizumab (see table below), talk to your healthcare professional. Your health professional may give you other medicines to prevent more severe complications and reduce your symptoms. Your health professional may withhold the next dose of Padcev, reduce the dose of Padcev or stop your treatment with Padcev. Side effects may be very common (may affect more than 1 in 10 people), common (may affect less than 1 in 10 but more than 1 in 100 people), uncommon (may affect less than 1 in 100 but more than 1 in 1,000 people), or rare (may affect less than 1 in 1,000 people).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (monotherapy and combination therapy)			
Hyperglycemia (high blood sugar): frequent need to urinate, increased thirst, blurred vision		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Peripheral neuropathy (damage to nerves): Weakness, numbness and pain in hands and feet		X	
COMMON (monotherapy and combination therapy)			
Cardiac problems (fast heart rate): heart beating faster than usual		X	
Eye problems: dry eye, blurry vision, increased tearing, vision changes		X	
Infusion Site Extravasation (drug leaks outside of the blood vessels): redness, pain, swelling, bruising, infection, or blisters at the infusion site			X
Respiratory symptoms and lung problems (lung inflammation): cough, shortness of breath, chest pain or discomfort		X	
RARE (monotherapy and combination therapy)			
Severe skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrosis): unexplained widespread skin pain, blisters on your skin and mucous membranes, hives, tongue swelling, a red or purple skin rash that spreads, or unexplained shedding of your skin			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Padcev will be stored by the healthcare professional at the hospital or clinic. The storage details are as follows:

Do not use this medicine after the expiry date. This date is listed on the carton and vial label after EXP. Your healthcare professional will check this date before you receive this medicine.

Store this medicine at 2°C to 8°C. Do not freeze. Do not shake. Do not expose to sunlight. Do not store any unused portion of the infusion solution for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

If you want more information about Padcev:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.Seagen.ca, or by calling 1-833-473-2436.

This leaflet was prepared by Seagen Inc.

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