



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Padcev (*enfortumab vedotin*)

An overview of Padcev and why it is authorised in the EU

### What is Padcev and what is it used for?

Padcev is a cancer medicine for treating adults with urothelial cancer (a cancer of the bladder and urinary tract).

Padcev is used on its own in patients whose cancer is advanced or metastatic (has spread to other parts of the body) and who have already had platinum-based chemotherapy and an immunotherapy targeting PD-1 or PD-L1.

Padcev can also be used in combination with pembrolizumab (another cancer medicine) when the cancer is metastatic or cannot be removed by surgery, and patients have not been treated yet.

It contains the active substance enfortumab vedotin.

### How is Padcev used?

Padcev is given as an infusion (drip) into a vein over 30 minutes. When Padcev is used on its own, the patient should have an infusion three times over the course of 28 days (on days 1, 8 and 15). When used with pembrolizumab, Padcev is given twice over the course of 21 days (on days 1 and 8).

Treatment should continue until the disease gets worse or the side effects become intolerable.

Padcev can only be obtained with a prescription, and a doctor experienced in the use of cancer medicines should start and supervise treatment. The doctor may stop treatment or reduce the dose if the patient experiences severe side effects. For more information about using Padcev, see the package leaflet or contact your doctor or pharmacist.

### How does Padcev work?

The active substance in Padcev, enfortumab vedotin, consists of an antibody (a type of protein) combined with another substance known as MMAE. The antibody first attaches to a protein on the surface of cancer cells to gain entry into the cells. Once the active substance is inside the cells, MMAE disrupts the cells' internal skeleton, causing cell death and helping to stop the cancer from getting worse or spreading.

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## **What benefits of Padcev have been shown in studies?**

Padcev was more effective than chemotherapy at prolonging patients' lives in a main study of 608 patients with advanced urothelial cancer who had already had platinum-based chemotherapy and an immunotherapy. In this study, patients treated with Padcev lived on average for around 13 months while those who had chemotherapy lived on average for 9 months.

Another study involving 886 patients with advanced or metastatic urothelial cancer who had not yet received treatment compared the benefits of Padcev in combination with pembrolizumab with those of platinum-based chemotherapy and gemcitabine (other cancer medicines). Patients treated with Padcev plus pembrolizumab lived on average for around 13 months without the disease getting worse, and for an average of 32 months overall. Patients treated with platinum-based chemotherapy and gemcitabine lived for an average of around 6 months without the disease getting worse, and for an average of around 16 months overall.

## **What are the risks associated with Padcev?**

For the full list of side effects and restrictions of Padcev, see the package leaflet.

When Padcev is used on its own, the most common side effects (which may affect more than 1 in 10 people) include alopecia (hair loss), tiredness, reduced appetite, peripheral sensory neuropathy (nerve damage affecting sensation of pain, temperature and touch), diarrhoea, nausea (feeling sick), itching, dysgeusia (taste disturbance), anaemia (low red blood cell counts), weight loss, rash, dry skin, dry eyes, vomiting, increased levels of liver enzymes and hyperglycaemia (high levels of blood sugar).

When Padcev is used in combination with pembrolizumab, the most common side effects include peripheral sensory neuropathy, itching, tiredness, diarrhoea, alopecia, rash, weight loss, decreased appetite, nausea, anaemia, dysgeusia, dry skin, increased levels of liver enzymes, hyperglycaemia, dry eyes, vomiting, hypothyroidism (an underactive thyroid gland) and neutropenia (low levels of neutrophils, a type of white blood cell).

## **Why is Padcev authorised in the EU?**

There are few treatment choices for patients with advanced or metastatic urothelial cancer. Padcev, on its own or in combination with pembrolizumab, was shown to prolong the life of these patients. The side effects of Padcev were considered acceptable for a cancer medicine with the measures in place to minimise the risks.

The European Medicines Agency decided that Padcev's benefits are greater than its risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Padcev?**

The company that markets Padcev will ensure that all healthcare professionals prescribing this medicine are given a patient information pack, which will include a patient card. The card will inform patients that treatment could cause severe skin reactions such as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) and advise them to seek immediate medical care if they have symptoms of these reactions.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Padcev have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Padcev are continuously monitored. Suspected side effects reported with Padcev are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Padcev**

Padcev received a marketing authorisation valid throughout the EU on 13 April 2022.

Further information on Padcev can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/padcev](https://ema.europa.eu/medicines/human/EPAR/padcev).

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