EMA/44899/2022
EMEA/H/C/005392

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 for patients whose cancer is advanced or has spread and who have already had platinum-based chemotherapy and an immunotherapy.

It contains the active substance enfortumab vedotin.

How is Padcev used?

It is given as an infusion (drip) into a vein over 30 minutes. The patient should have an infusion three times over the course of 28 days (on days 1, 8 and 15) and should continue treatment 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.

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What are the risks associated with Padcev?

The most common side effects with Padcev (which may affect more than 1 in 10 people) are hair loss, tiredness, reduced appetite, nerve damage affecting sensation of pain, temperature and touch, diarrhoea, nausea, itching, taste disturbance, anaemia (low red blood cell counts), weight loss, rash, dry skin, vomiting, increased levels of liver enzymes and high levels of blood sugar.

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

Why is Padcev authorised in the EU?

There are few choices for patients with urothelial cancer who have had platinum-based chemotherapy and an immunotherapy. A main study showed that Padcev can help prolong life in these patients, and the side effects of the medicine were similar to those that occur after chemotherapy.

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

This overview was last updated in 04-2022.