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Tivdak (*tisotumab vedotin*)

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

What is Tivdak and what is it used for?

Tivdak is a cancer medicine used to treat adults with cervical cancer (a cancer of the cervix) when the disease has worsened during or after previous systemic (whole-body) treatment. It is used on its own in patients whose cancer has come back or is metastatic (has spread to other parts of the body).

Tivdak contains the active substance tisotumab vedotin.

How is Tivdak used?

Tivdak can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in the use of cancer treatments.

Tivdak is given by infusion (drip) into a vein over 30 minutes, every 3 weeks. Treatment should be continued until the disease gets worse or the patient gets unacceptable side effects. The doctor may decide to reduce the dose or interrupt treatment if certain side effects occur.

The patient's eyes and eyesight should be checked by an eye specialist before starting treatment with Tivdak and at any point during treatment if the patient gets new, or worsening, eye symptoms.

For more information about using Tivdak, see the package leaflet or contact your doctor or pharmacist.

How does Tivdak work?

The active substance in Tivdak, tisotumab vedotin, is an antibody (a type of protein) combined with another substance known as MMAE (a chemotherapy medicine). The antibody first attaches to tissue factor (TF), a protein found on the surface of certain cancer cells, to enter these cells. Once inside the cells, MMAE disrupts the cells' internal skeleton, causing cell death and helping to prevent the cancer from getting worse or spreading.

What benefits of Tivdak have been shown in studies?

The benefits of Tivdak were evaluated in a study involving 502 patients with cervical cancer which had come back or was metastatic, after one or two systemic treatments, including one chemotherapy.

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In this study, Tivdak was compared with chemotherapy, as chosen by the doctor for each patient. Patients who received Tivdak lived on average for 11.5 months while those who received chemotherapy lived for an average of 9.5 months. In addition, patients who received Tivdak lived on average for around 4 months without their disease getting worse, compared to around 3 months for those given chemotherapy.

What are the risks associated with Tivdak?

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

The most common side effects with Tivdak (which may affect more than 1 in 10 people) include peripheral neuropathy (nerve damage in arms and legs causing pain or numbness, burning and tingling), nausea (feeling sick), nosebleed, conjunctivitis (redness and discomfort in the eye), hair loss, anaemia (low levels of red blood cells) and diarrhoea.

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include abdominal (belly) pain, constipation, fever, peripheral neuropathy and vomiting. Side effects that led to death were reported in 2% of patients in the studies.

Why is Tivdak authorised in the EU?

At the time of authorisation, there were few treatment choices for patients with cervical cancer whose cancer has come back or is metastatic and worsened after previous treatment. Tivdak was shown to prolong survival and delay the worsening of the disease, making it an additional treatment option for these patients.

Regarding safety, Tivdak's side effects differ from those seen with chemotherapy. They can be serious and life-threatening, and include eye toxicity, peripheral neuropathy and bleeding. The agency considered that the side effects are manageable with the measures in place to minimise the risks; the company that markets Tivdak will provide further data on the long-term safety of the medicine.

The European Medicines Agency therefore decided that Tivdak'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 Tivdak?

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

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

Other information about Tivdak

Tivdak received a marketing authorisation valid throughout the EU on 28 March 2025.

Further information on Tivdak can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/tivdak.

This overview was last updated in 03-2025.