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EPAR summary for the public

Javlor

vinflunine

This is a summary of the European public assessment report (EPAR) for Javlor. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Javlor.

What is Javlor?

Javlor is a concentrate for solution for infusion (drip into a vein). It contains the active substance vinflunine (25 mg/l).

What is Javlor used for?

Javlor is used for the treatment of adults with advanced or metastatic 'transitional cell carcinoma of the urothelial tract' (a cancer that affects the lining of the bladder and the rest of the urinary tract). 'Metastatic' means that the cancer has spread to other parts of the body. Javlor is used when previous treatment with a platinum-containing anticancer medicine has failed.

The medicine can only be obtained with a prescription.

How is Javlor used?

Treatment with Javlor should be started under the supervision of a doctor qualified to use anticancer medicines and is only given in specialised hospital units. Before administering Javlor, patients should have a blood test to check their blood cell and haemoglobin levels. This is because low levels of haemoglobin (a protein found in red blood cells that carries oxygen around the body) and blood cells (white blood cells and platelets) are frequent side effect of the medicine.

The dose of Javlor to be given is based on the patient's body surface area (calculated using height and weight). The recommended dose is 320 mg per m^2. Javlor is given as a drip into a vein over a period of

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20 minutes once every three weeks. The doctor may need to adjust the dose by taking into account the patient's age, liver or kidney function and certain side effects that the patient may be experiencing. The doctor may also delay or stop doses if the patient experiences certain side effects, including low levels of platelets and neutrophils (a type of white blood cell), and certain side effects affecting the heart, liver or lungs. Measures to prevent constipation, such as laxatives, are recommended after Javlor is given in the first week. For more information, see the summary of product characteristics (also part of the EPAR).

How does Javlor work?

The active substance in Javlor, vinflunine, belongs to the group of anticancer medicines known as the vinca alkaloids. It attaches to a protein in cells called 'tubulin', which is important in the formation of the internal 'skeleton' that cells need to assemble when they divide. By attaching to tubulin in cancer cells, vinflunine stops the formation of the skeleton, preventing the division and spread of the cancer cells.

How has Javlor been studied?

In one main study of 370 adults with advanced or metastatic transitional cell carcinoma of the urothelial tract, patients who were given Javlor treatment were compared with patients who were not given any anticancer medicine. During the study all patients received best supportive care (any medicines or techniques to help patients, but not other anticancer medicines). All the patients had previously received treatment with a platinum-containing medicine which failed. The main measure of effectiveness was how long the patients lived. The study also looked separately at the results in eligible patients who fulfilled strict criteria such as having had a worsening of the disease after treatment with a platinum-containing medicine.

What benefit has Javlor shown during the studies?

Javlor with best supportive care was more effective than best supportive care alone in prolonging the lives of patients with advanced or metastatic transitional cell carcinoma of the urothelial tract. Among all patients in the study, there was no clear evidence of a difference in survival between patients who received Javlor and those who did not. However, there was a difference among patients who fulfilled the strict criteria entry requirements for the study. In this group, those given Javlor lived for 6.9 months compared with 4.3 months for patients who were not given the Javlor.

What is the risk associated with Javlor?

The most common side effects with Javlor (seen in more than 1 patient in 10) are neutropenia, leucopenia (low white blood cell counts), anaemia (low red blood cell counts), thrombocytopenia (low platelet count), loss of appetite, constipation, abdominal (stomach) pain, vomiting, nausea (feeling sick), stomatitis (inflammation of the lining of the mouth), diarrhoea, alopecia (hair loss), myalgia (muscle pain), asthenia (weakness) or fatigue (tiredness), injection site reaction, fever and weight loss. For the full list of all side effects reported with Javlor, see the package leaflet.

Javlor must not be used in people who are hypersensitive (allergic) to vinflunine or other vinca alkaloids. It must not be used in patients who have or have had a severe infection within the past two weeks or in patients with a neutrophil count of less than 1,500 per mm^3 for the first administration or less than 1,000/mm^3 for subsequent administrations or a platelet count less than 100,000 per mm^3. It must also not be used in breastfeeding mothers.

Why has Javlor been approved?

The CHMP decided that Javlor's benefits are greater than its risks and recommended that Javlor be given marketing authorisation.

Other information about Javlor

The European Commission granted a marketing authorisation valid throughout the European Union for Javlor on 21 September 2009.

The full EPAR for Javlor can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Javlor, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2012.