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EPAR summary for the public

Jevtana

cabazitaxel

This is a summary of the European public assessment report (EPAR) for Jevtana. 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 Jevtana.

What is Jevtana and what is it used for?

Jevtana is a cancer medicine used to treat men with metastatic castration-resistant prostate cancer. This is cancer that affects the prostate gland in men that produces the liquid in semen. Jevtana is used when the cancer has spread to other parts of the body (metastatic) despite treatments to prevent the production of testosterone or after surgical removal of the testes (castration). Jevtana is used in combination with prednisone or prednisolone (anti-inflammatory medicines) in patients who have previously been treated with docetaxel (another cancer medicine).

Jevtana contains the active substance cabazitaxel.

How is Jevtana used?

Jevtana can only be obtained with a prescription and should only be used in units specialising in chemotherapy (medicines to treat cancer) under the supervision of a doctor experienced in the use of chemotherapy.

Jevtana is available as a concentrate and a solvent to be made up into a solution for infusion (drip) into a vein. It is given once every three weeks as an infusion lasting one hour, at a dose of 25 mg per square metre body surface area (calculated using the patient's weight and height). It is given in combination with prednisone or prednisolone, taken daily throughout treatment.

The dose of Jevtana should be reduced or treatment stopped if the patient has certain side effects. The doses should also be reduced in patients with mildly or moderately reduced liver function.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Before receiving Jevtana infusions, patients should first be given medicines to prevent allergic reactions and medicines to prevent vomiting.

For more information, see the package leaflet.

How does Jevtana work?

The active substance in Jevtana, cabazitaxel, belongs to the group of cancer medicines known as 'taxanes'. Cabazitaxel works by blocking the ability of cancer cells to break down their internal 'skeleton' that allows them to divide and multiply. With their skeleton still in place, the cells cannot divide and they eventually die. Jevtana also affects non-cancer cells, such as blood and nerve cells, which can cause side effects.

What benefits of Jevtana have been shown in studies?

Jevtana prolonged overall survival (the average length of time the patients lived) in one main study involving 755 men with metastatic castration-resistant prostate cancer who had previously been treated with docetaxel. The effects of Jevtana were compared with another cancer medicine, mitoxantrone. Both medicines were given in combination with prednisone or prednisolone. The average overall survival for patients treated with Jevtana was 15.1 months compared with 12.7 months for patients given mitoxantrone.

What are the risks associated with Jevtana?

The most common side effects with Jevtana (seen in more than 1 patient in 10) include anaemia (low red blood cell counts), leucopenia (low white blood cell counts), neutropenia (low counts of neutrophils, a type of white blood cell), thrombocytopenia (low blood platelet counts) and diarrhoea. Some of these effects were severe. For the full list of all side effects reported with Jevtana, see the package leaflet.

Jevtana must not be used in people who are hypersensitive (allergic) to cabazitaxel, to any other taxane, or to any of the other ingredients. It must not be given to patients whose blood neutrophil count is below 1,500/mm^3, who have severely reduced liver function or who recently received or are about to receive a yellow fever vaccine.

Why has Jevtana been approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that the ability of Jevtana to prolong overall survival in castration-resistant metastatic prostate cancer patients was clinically important. It decided that Jevtana's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Jevtana?

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

Other information about Jevtana

The European Commission granted a marketing authorisation valid throughout the European Union for Jevtana on 17 March 2011.

The full EPAR for Jevtana 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 Jevtana, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2017.