EMA/242602/2020
EMEA/H/C/005178

Cabazitaxel Accord (*cabazitaxel*)

An overview of Cabazitaxel Accord and why it is authorised in the EU

What is Cabazitaxel Accord and what is it used for?

Cabazitaxel Accord is a cancer medicine used to treat men with metastatic castration-resistant prostate cancer. This is a cancer that affects the prostate gland that produces the liquid in semen (prostate fluid). Cabazitaxel Accord 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). Cabazitaxel Accord is used in combination with prednisone or prednisolone (anti-inflammatory medicines) in patients who have previously been treated with docetaxel (another cancer medicine).

Cabazitaxel Accord contains the active substance cabazitaxel and is a 'hybrid' and a 'generic' medicine. This means that it is similar to a reference medicine containing the same active substance, but comes in a different concentration and is prepared (diluted) differently. The reference medicine for Cabazitaxel Accord is Jevtana.

How is Cabazitaxel Accord used?

Cabazitaxel Accord 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.

Cabazitaxel Accord is available as a concentrate 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 based on the patient's weight and height. It is given in combination with prednisone or prednisolone, taken daily throughout treatment.

The doctor may have to reduce the dose of Cabazitaxel Accord or stop treatment if the patient has certain side effects. The dose should also be reduced in patients with mildly reduced liver function. Cabazitaxel Accord must not be given to patients with moderately or severely reduced liver function.

Before receiving Cabazitaxel Accord infusion, patients should first be given medicines to prevent allergic reactions and medicines to prevent vomiting.

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

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

How does Cabazitaxel Accord work?

The active substance in Cabazitaxel Accord, 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', which allows them to divide and multiply. With their skeleton still in place, the cells cannot divide and eventually die. Cabazitaxel Accord also affects non-cancer cells, such as blood and nerve cells, which can cause side effects.

How has Cabazitaxel Accord been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Jevtana, and do not need to be repeated for Cabazitaxel Accord.

As for every medicine, the company provided studies on the quality of Cabazitaxel Accord. There was no need for bioequivalence studies to investigate whether Cabazitaxel Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Cabazitaxel Accord is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Cabazitaxel Accord?

Because Cabazitaxel Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Cabazitaxel Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Cabazitaxel Accord has been shown to have comparable quality and to be bioequivalent to Jevtana. Therefore, the Agency's view was that, as for Jevtana, the benefits of Cabazitaxel Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Cabazitaxel Accord

Cabazitaxel Accord received a marketing authorisation valid throughout the EU on 28 August 2020.

Further information on Cabazitaxel Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cabazitaxel-accord.

This overview was last updated in 05-2020.