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Cabazitaxel Accord: Letter to healthcare professionals about risk of mix-ups with Jevtana (cabazitaxel)

Differences in strengths and dilution for Cabazitaxel Accord and Jevtana

The European Medicines Agency (EMA) is alerting healthcare professionals of a risk of medication errors and mix-ups with the cancer medicine cabazitaxel: Jevtana and Cabazitaxel Accord. Both medicines are given by infusion (drip) into a vein but come in different strengths and require different dilution steps.

Cabazitaxel Accord comes in a vial containing 3 ml of a concentrate (20 mg/ml) to make a solution for infusion in a single dilution step. In contrast, Jevtana comes in a vial containing 1.5 ml of concentrate (60 mg/1.5 ml) together with a vial containing solvent which is used to make a solution for infusion in a two-step dilution process.

A mix-up with these medicines and their strengths and dilution requirements may result in healthcare professionals inadvertently giving their patients too much (overdose) or not enough (underdose) of the active substance. Underdosing may result in an inadequate effect, while overdosing can result in serious and potentially fatal complications such as suppression of the bone marrow (which produces blood cells) and serious gastrointestinal disorders.

A letter will therefore be sent to healthcare professionals using Cabazitaxel Accord or Jevtana, alerting them to the differences in strengths and reminding them to carefully follow the dilution instructions that are provided with the medicine.

Information for healthcare professionals

- The injectable medicine cabazitaxel is available in two presentations of different strengths that require different reconstitution steps:
  - Cabazitaxel Accord as a 20 mg/ml concentrate for solution for infusion requiring a single-step dilution process.
  - Jevtana as a 60 mg/1.5 ml concentrate with solvent for solution for infusion requiring a two-step dilution process.
- Before the final dilution step either in glucose solution or sodium chloride solution for infusion, the concentration of cabazitaxel is:

  20 mg/ml for Cabazitaxel Accord

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10 mg/ml for Jevtana.

- When prescribing and preparing Cabazitaxel Accord or Jevtana, healthcare professionals should be aware of the potential for medication errors and carefully follow the instructions provided in the summary of product characteristics of the medicine.
- To help differentiate between the two presentations, the outer carton contains a warning and the vials have distinctive features. A summary of the differences is provided below:

	Cabazitaxel Accord 20 mg/ml concentrate for solution for infusion	**Jevtana 60 mg/1.5 ml concentrate and solvent for solution for infusion**
Presentation	One ready-to-use vial: • Concentrate (3 ml) sealed by an aluminium cap covered with a **violet** plastic flip-off cap	Two vials: • Concentrate (1.5 ml) sealed by an aluminium cap covered with a **light green** plastic flip-off cap • Solvent (4.5 ml) sealed by a gold-coloured aluminium cap covered with a **colourless** plastic flip-off cap
Carton warning	"For intravenous use after dilution"	"For intravenous infusion only after **second** dilution"
Concentration of cabazitaxel in vial before the final dilution step	**20 mg/ml**	**10 mg/ml**

More about the medicines

Cabazitaxel Accord and Jevtana are cancer medicines 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.

Cabazitaxel Accord or Jevtana are 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 or Jevtana are used in combination with prednisone or prednisolone (anti-inflammatory medicines) in patients who have previously been treated with docetaxel (another cancer medicine).

More information on Jevtana and Cabazitaxel Accord can be found on the Agency's website:

- https://www.ema.europa.eu/en/medicines/human/EPAR/jevtana
- https://www.ema.europa.eu/en/medicines/human/EPAR/cabazitaxel-accord