Direct Healthcare Professional Communication

16/06/2021

Cabazitaxel Accord 20 mg/mL concentrate for solution for infusion:

Risk of medication errors and mix-up with Jevtana (60 mg/1.5 mL) concentrate and solvent for solution for infusion

Dear Healthcare Professional,

Accord Healthcare S.L.U., Spain in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you for the following:

Summary

- **There is a risk of medication errors due to the presence on the market of different cabazitaxel presentations:**
    - **Cabazitaxel Accord (20 mg/mL) concentrate for solution for infusion requires a single-step dilution process;**
    - **Jevtana (60 mg/1.5 mL) concentrate and solvent for solution for infusion requires 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**
    - **10 mg/ml for Jevtana**
- **A mix-up between the products may lead to medication errors resulting in either overdosing with potentially fatal outcome, or underdosing with reduction of therapeutic effect (see background section below).**
- **Always check carefully which product is being used and the dilution instructions to ensure that the patient receives the correct dose of cabazitaxel.**

Background information

Cabazitaxel is indicated in combination with prednisone or prednisolone for the treatment of adults with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing regimen.

Differences between Cabazitaxel Accord and Jevtana

	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 (3 ml of concentrate) 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 resulting in infusion solution	**20 mg/ml**	**10 mg/ml**

The consequences of medication errors due to possible mix-ups between two different products are:

- **Risk associated with overdosing:** exacerbation of adverse reactions as bone marrow suppression and gastrointestinal disorders which may result in a potential fatal outcome. Please refer to section 4.9 "overdosing" of the SmPC describing how to manage overdosing.

- **Risk associated with underdosing:** suboptimal response to therapy resulting in the possibility of cancer chemotherapy resistance with a reduced clinical response.

Call for reporting

Suspected adverse reactions and any **medication error** (any errors while prescribing, preparing or administering the drug) should be reported in accordance with the national spontaneous reporting system <to be filled nationally as per local requirement>.

Company contact point

<To be filled nationally as per local requirement>