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 <u>single-step</u> dilution process;**
    - **Jevtana (60 mg/1.5 mL) concentrate and solvent for solution for infusion requires a <u>two-step</u> 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>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Cabazitaxel Accord 20 mg/mL concentrate for solution for infusion
Marketing authorisation holder(s)	Accord Healthcare S.L.U., Spain
Safety concern and purpose of the communication	**Risk of medication errors and mix-up with Jevtana (60 mg/1.5 mL) concentrate and solvent for solution for infusion**
DHPC recipients	Oncologists, hospital nurses, hospital pharmacists and other recipients to be agreed with the National Competent Authorities
Member States where the DHPC will be distributed	All Member states where Cabazitaxel Accord 20 mg/mL concentrate for solution for infusion is launched

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	17 April 2020
DHPC and communication plan (in English) agreed by CHMP	30 April 2020
Submission of translated DHPCs to the national competent authorities for review	30 calendar days from CHMP adoption
Agreement of translations by national competent authorities	To be agreed at national level
Dissemination of DHPC	At time of the launch of the product at the latest