

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
201023

MEDICAL REVIEW(S)

CLINICAL REVIEW

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Established Name Cabazitaxel
Proposed Trade Name Jevtana
Therapeutic Class Taxane
Applicant Sanofi-Aventis

Formulation Intravenous
Dosing Regimen 25 mg/m² IV over 1 hour every
21 days
Indication Hormone-refractory prostate
cancer
Intended Population Men with metastatic hormone-
refractory prostate cancer who
have previously received a
docetaxel-containing regimen

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