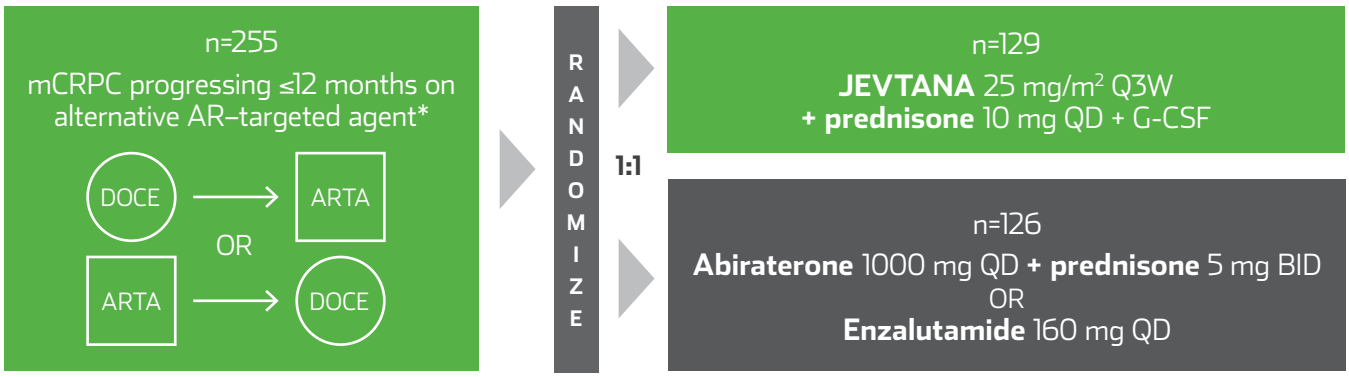
CABAZITAXEL VERSUS ABIRATERONE OR ENZALUTAMIDE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

JEVTANA® (cabazitaxel) injection

Dear Healthcare Provider,

Sanofi Genzyme is pleased to announce the results of the CARD study that was published in the *New England Journal of Medicine* and presented at ESMO 2019 and ASCO GU 2020. This prospective randomized trial evaluated the efficacy and safety of JEVTANA vs. an androgen receptor-targeted agent (abiraterone or enzalutamide) in metastatic castration resistant prostate cancer (mCRPC). The primary endpoint was imaging-based progression-free survival (rPFS†) and secondary endpoints included overall survival, tumor response, and safety.

CARD Study Design: A randomized, open-label, multicenter study in patients (n=255) with mCRPC who had previously received docetaxel and had disease progression within 12 months on an alternative androgen receptor-targeted agent. The CARD trial was an open label trial with no blinded central review of the standard imaging and was sponsored by Sanofi.



*enzalutamide or abiraterone

ARTA=androgen receptor–targeted agent; BID=twice a day; DOCE=docetaxel; G-CSF=granulocyte-colony stimulating factor; Q3W=every 3 weeks; QD=once daily. Median follow-up was 9.2 months from randomization until the end of the study.[1]

†rPFS (radiographic progression-free survival) was defined as the time from randomization to the occurrence of one of the following events: radiological tumor progression using RECIST 1.1 (except for lymph nodes: if lymph node metastasis is the only evidence of metastasis at baseline, it must be ≥20 mm in diameter when measured by spiral CT or MRI (as defined by PCWG2)), progression of bone lesions according to PCWG2 criteria, or death.

KEY PATIENT ELIGIBILITY CRITERIA

- Histologically confirmed prostate cancer and castrate levels of testosterone (<0.5 ng/ml)
- Prior treatment with docetaxel (at least 3 cycles; before or after AR-targeted agent)
- Progression within 12 months with abiraterone or enzalutamide (before or after docetaxel)

INDICATION

JEVTANA is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

IMPORTANT SAFETY INFORMATION

WARNING: NEUTROPENIA AND HYPERSENSITIVITY

Neutropenia: Neutropenic deaths have been reported. Monitor for neutropenia with frequent blood cell counts. JEVTANA is contraindicated in patients with neutrophil counts of ≤1,500 cells/mm³. Primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features.

Severe hypersensitivity: Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the JEVTANA infusion and administration of appropriate therapy. Patients should receive premedication. JEVTANA is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

CARD: The first comparative, prospective phase 4 trial of JEVTANA (cabazitaxel) vs abiraterone or enzalutamide in patients with mCRPC[1]

Summary of Demographic and Patient Characteristics[1,6*]		JEVTANA 25 mg/m² + prednisone (n=129)	Abiraterone or enzalutamide (n=126)
Age	Median (range)	70 (46-85)	71 (45-88)
	≥75 (%)	34.9	27.0
ECOG PS, No. (%)†	0,1	123 (95.3)	119 (94.4)
	2	6 (4.7)	7 (5.6)
Disease site, No. (%)	Bone (+/- lymph nodes)	74 (57.4)	76 (60.3)
	Lymph nodes	8 (6.2)	6 (4.8)
	Liver	11 (8.5)	18 (14.3)
	Lung	10 (7.8)	7 (5.6)
PSA, ng/mL	Median (range)	62.0 (1.1-15,000.0)	60.5 (1.5-2868.0)
Lactate dehydrogenase, IU/L	Median (range)	248.0 (135-2753)	251.0 (50-3374)
Type of progression at trial entry, No. (%)	PSA only	11 (8.5)	10 (7.9)
	Imaging-based, with or without PSA progression	23 (17.8)	16 (12.7)
	Pain, with or without PSA or imaging-based progression	86 (66.7)	90 (71.4)
	Missing data	9 (7.0)	10 (7.9)

AR-targeted agent=abiraterone or enzalutamide.
*Plus-minus values are means ffl standard deviation.
†ECOG PS scores are on a 5-point scale, with higher numbers indicating greater disability.

Disease History		JEVTANA 25 mg/m² + prednisone (n=129)	Abiraterone or enzalutamide (n=126)
M1 disease at diagnosis, No (%)*		49 (38.0)	60 (47.6)
Gleason score 8-10 at diagnosis, No. (%)†		73 (56.6)	81 (64.3)
First ADT	Median duration, months (range)	13.7 (2-114)	12.6 (3-179)
Previous AR-targeted agent No. (%)‡	Abiraterone	56 (43.4)	67 (53.2)
	Enzalutamide	72 (55.8)	59 (46.8)
Timing of previous AR-targeted agent, No. (%)	Before docetaxel	50 (38.8)	49 (38.9)
	After docetaxel	79 (61.2)	77 (61.1)

*M1 disease was defined as metastatic disease (distant metastases).
†Gleason scores range from 2 to 10, with scores of 8 to 10 indicating a high-grade cancer.
‡One patient (0.8%) had missing data in the JEVTANA group.

SCROLL DOWN TO ACCESS JEVTANA DATA

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

JEVTANA is contraindicated in patients with neutrophil counts of ≤1,500/mm^3, patients with a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80, and patients with severe hepatic impairment (total bilirubin >3x upper limit of normal (ULN)).

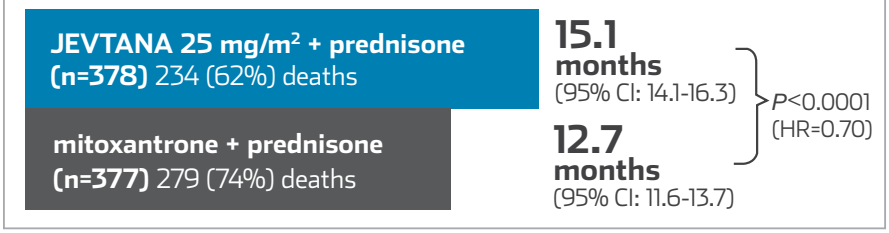
Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

A National Comprehensive Cancer Network® (NCCN®) Designated Category 1 Second-Line Therapy Options in mCRPC[2] After Docetaxel

TROPIC Study

JEVTANA was validated as a treatment in mCRPC after docetaxel: The TROPIC trial was a randomized, open-label, international, multicenter study of JEVTANA 25 mg/m^2 (n=378) vs. mitoxantrone 12 mg/m^2 (n=377) in patients with mCRPC previously treated with a docetaxel-containing treatment regimen. The primary endpoint was overall survival (OS).

JEVTANA Significantly Prolonged Median OS[3,4]



JEVTANA significantly reduced risk of death by 30% vs mitoxantrone, an active comparator (95% CI: 0.59-0.83).

JEVTANA delivered a ≥30% reduction in tumors (RECIST criteria) in 3x more mCRPC patients vs mitoxantrone, an active comparator: 14.4% (29/201) (95% CI: 9.6-19.3) vs 4.4% (9/204) (95% CI: 1.6-7.2) (*P*=0.0005).

The safety of JEVTANA + prednisone (n=371) was evaluated in mCRPC patients treated in the TROPIC trial, compared to mitoxantrone + prednisone (n=371).

- The most common (≥10%) grade 1-4 adverse reactions in patients who received JEVTANA vs mitoxantrone were anemia (98% vs 82%, respectively), leukopenia (96% vs 93%), neutropenia (94% vs 87%), thrombocytopenia (48% vs 43%), diarrhea (47% vs 11%), fatigue (37% vs 27%), nausea (34% vs 23%), vomiting (22% vs 10%), constipation (20% vs 15%), asthenia (20% vs 12%), abdominal pain (17% vs 6%), hematuria (17% vs 4%), back pain (16% vs 12%), anorexia (16% vs 11%), peripheral neuropathy (13% vs 3%), pyrexia (12% vs 6%), dyspnea (12% vs 4%), dysgeusia (11% vs 4%), cough (11% vs 6%), arthralgia (11% vs 8%), and alopecia (10% vs 5%)
- The most common (≥5%) grade 3-4 adverse reactions in patients who received JEVTANA vs mitoxantrone were neutropenia (82% vs 58%), leukopenia (69% vs 42%), anemia (11% vs 5%), febrile neutropenia (7% vs 1%), diarrhea (6% vs <1%), fatigue (5% vs 3%), and asthenia (5% vs 2%)

PROSELICA Study

JEVTANA 20 mg/m^2 recommended dose was established in the PROSELICA Trial: The trial was a non-inferiority, multicenter, randomized, open-label study of JEVTANA 20 mg/m^2 (n=598) vs. JEVTANA 25 mg/m^2 (n=602) in patients with mCRPC previously treated with a docetaxel-containing regimen. The primary endpoint was overall survival (OS).

20 mg/m^2 Delivered Median OS Comparable to 25 mg/m^2 [5]

Per-protocol population

Per intent-to-treat population: 13.4 months (95% CI: 12.2-14.9) median OS for JEVTANA 20 mg/m^2 and 14.5 months (95% CI: 13.5-15.3) for JEVTANA 25 mg/m^2 (HR=1.024) (97.78% CI: 0.886-1.184).

No notable difference in OS was observed in subgroups based on the stratification factors, ECOG performance status score, measurability of disease, or region.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Bone Marrow Suppression (BMS): BMS manifested as neutropenia, anemia, thrombocytopenia and/or pancytopenia may occur. Neutropenic deaths have been reported. Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed. Primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features. Monitoring of complete blood counts is essential on a weekly basis during cycle 1 and before each treatment cycle thereafter so that the dose can be adjusted, if needed. Caution is recommended in patients with hemoglobin <10 g/dl.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

Incidence of Hematologic Laboratory Abnormalities with JEVTANA (cabazitaxel) 20 mg/m^2 vs 25 mg/m^2

Hematologic Laboratory Abnormalities in the PROSELICA Trial[1]

	JEVTANA 20 mg/m^2 + prednisone n=577	JEVTANA 25 mg/m^2 + prednisone n=590	JEVTANA 20 mg/m^2 + prednisone n=577	JEVTANA 25 mg/m^2 + prednisone n=590
Laboratory Abnormality	**Grade 1–4**		**Grade 3–4**	
Neutropenia	67%	89%	42%	73%
Anemia	99.8%	99.7%	10%	14%
Leukopenia	80%	95%	29%	60%
Thrombocytopenia	35%	43%	3%	4%

Incidence of Adverse Reactions (ARs)* with JEVTANA 20 mg/m^2 vs 25 mg/m^2 in the PROSELICA Trial

ARs ≥5% in the PROSELICA Trial[1]

	JEVTANA 20 mg/m^2 + prednisone n=580	JEVTANA 25 mg/m^2 + prednisone n=595	JEVTANA 20 mg/m^2 + prednisone n=580	JEVTANA 25 mg/m^2 + prednisone n=595
Adverse Reaction	**Grade 1–4**		**Grade 3–4**	
Diarrhea	31%	40%	1%	4%
Nausea	25%	32%	0.7%	1%
Fatigue	25%	27%	3%	4%
Constipation	18%	18%	0.3%	0.7%
Vomiting	15%	18%	1.2%	1%
Asthenia	15%	20%	2%	2%
Hematuria	14%	21%	2%	4%
Decreased appetite	13%	19%	0.7%	1%
Back pain	11%	14%	0.9%	1%
Bone pain	8%	8%	2%	2%
Arthralgia	8%	7%	0.5%	0.8%
Urinary tract infection†	7%	11%	2%	2%
Dysgeusia	7%	11%	0	0
Peripheral sensory neuropathy	7%	11%	0	0.7%
Edema peripheral	7%	9%	0.2%	0.2%
Cough	6%	6%	0	0
Abdominal pain	6%	9%	0.5%	1%
Headache	5%	4%	0.2%	0.2%
Dyspnea	5%	8%	0.9%	0.7%
Stomatitis	5%	5%	0	0.3%
Pain in extremity	5%	7%	0.2%	0.5%
Dysuria	5%	4%	0.3%	0
Pyrexia	5%	6%	0.2%	0.2%
Dizziness	4%	5%	0	0
Weight decreased	4%	7%	0.2%	0
Neutropenia‡	3%	11%	2%	10%
Neutropenic infection§	3%	7%	2%	6%
Alopecia	3%	6.1%	0	0
Febrile Neutropenia	2%	9%	2%	9%
Wrong technique in drug usage process	0.3%	5%	0	0

*Grade from NCI CTCAE version 4.03. †Includes urinary tract infection staphylococcal, urinary tract infection bacterial, urinary tract infection fungal, and urosepsis. ‡Based on adverse event reporting. §Includes neutropenic sepsis.

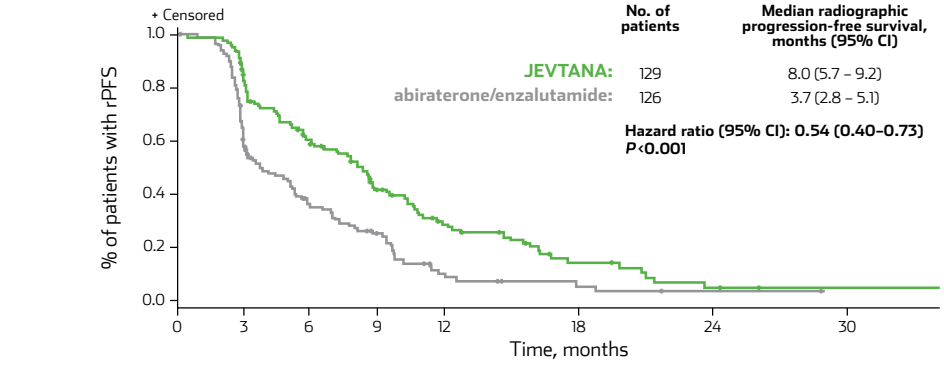
- 17% of patients on 20 mg/m^2 and 20% of patients on 25 mg/m^2 discontinued due to ARs. The most common ARs leading to treatment discontinuation were fatigue and hematuria.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

CARD Study

JEVTANA (cabazitaxel) significantly improved rPFS (radiographic progression free survival) and OS (overall survival) compared with abiraterone or enzalutamide

Primary Endpoint – rPFS (months) – ITT Population

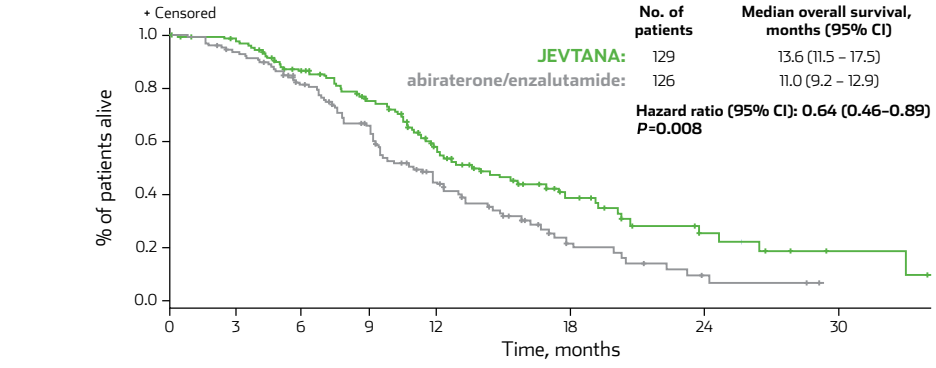


NO. AT RISK:

JEVTANA:	129	91	64	41	23	9	2	1
abiraterone/ enzalutamide:	126	61	36	22	7	3	1	0

46% relative reduction in risk of radiographic progression or death[1]

Secondary Endpoint – OS (months) – ITT Population



NO. AT RISK:

JEVTANA:	129	122	96	77	51	21	8	2
abiraterone/ enzalutamide:	126	116	88	64	39	11	3	0

36% relative reduction in risk of death[1]

At the cutoff date, 153 deaths were noted, with 70 deaths (54.3%) occurring in the JEVTANA group and 83 (65.9%) in the abiraterone or enzalutimde group.

The 25 mg/m^2 dose of JEVTANA was used in the CARD trial, which was conducted in Europe (in the European label, the recommended starting dose of JEVTANA is 25 mg/m^2).

All efficacy analyses were performed on the intention-to-treat population, at the cut-off date for 196 rPFS events.

After progression, the choice of subsequent anti-cancer treatment was at the discretion of the investigator. Of 126 patients randomized to an androgen receptor-targeted agent, 42 (33.3%) received cabazitaxel after progression. Of 129 patients randomized to cabazitaxel, 30 patients (23.3%) received abiraterone or enzalutamide after progression.

TREATMENT DURATION[1] – Median 7 cycles with JEVTANA and 4 cycles with androgen-receptor-targeted agent. A treatment cycle was 3 weeks in both trial groups.

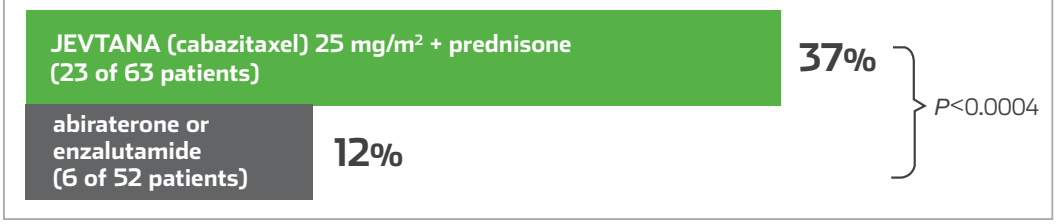
IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS cont'd

Increased Toxicities in Elderly Patients: Patients ≥65 years of age were more likely to experience fatal outcomes not related to disease progression and certain adverse reactions, including neutropenia and febrile neutropenia. Monitor closely.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

Secondary Endpoint – Tumor Resonse (patients with measureable disease at baseline)



Partial response was measured by RECIST criteria, which is defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

CARD – Safety[1]

Adverse events (AEs) grade ≥3 occurred at similar rates for both treatment groups.[1]

AE of any grade reported in ≥10% and/or grade ≥3 reported in ≥3% of patients in either treatment arm (safety population), No. (%)[6]

	JEVTANA 25 mg/m² + prednisone (n=126)		abiraterone or enzalutamide (n=124)	
Adverse event	**All Grades**	**Grade ≥3**	**All Grades**	**Grade ≥3**
Asthenia/fatigue	67 (53.2)	5 (4.0)	45 (36.3)	3 (2.4)
Diarrhea	50 (39.7)	4 (3.2)	8 (6.5)	0
Infection	40 (31.7)	10 (7.9)	25 (20.2)	9 (7.3)
Musculoskeletal pain/discomfort*	34 (27.0)	2 (1.6)	49 (39.5)	7 (5.6)
Nausea/vomiting	33 (26.2)	0	29 (23.4)	2 (1.6)
Peripheral neuropathy	25 (19.8)	4 (3.2)	4 (3.2)	0
Constipation	19 (15.1)	0	13 (10.5)	0
Hematuria	19 (15.1)	1 (0.8)	7 (5.6)	2 (1.6)
Decreased appetite	17 (13.5)	1 (0.8)	19 (15.3)	3 (2.4)
Dysgeusia	14 (11.1)	0	5 (4.0)	0
Renal disorder†	8 (6.3)	4 (3.2)	14 (11.3)	10 (8.1)
Cardiac disorder	8 (6.3)	1 (0.8)	10 (8.1)	6 (4.8)
Arthralgia	8 (6.3)	0	16 (12.9)	1 (0.8)
Spinal cord or nerve root disorder‡	6 (4.8)	3 (2.4)	9 (7.3)	5 (4.0)
Psychiatric disorder§	5 (4.0)	0	15 (12.1)	0
Febrile neutropenia	4 (3.2)	4 (3.2)	0	0

Deaths (Intention-to-treat Population), No. (%)[6]	**JEVTANA 25 mg/m² + prednisone (n=129)**	**abiraterone or enzalutamide (n=126)**
Deaths by the cutoff date	70 (54.3)	83 (65.9)
AE leading to death (fatal outcome)**	7 (5.6)	14 (11.3)

AEs (Safety Population), No. (%)[6]	**JEVTANA 25 mg/m² + prednisone (n=126)**	**abiraterone or enzalutamide (n=124)**
Any AE	124 (98.4)	117 (94.4)
Grade ≥3 AE	71 (56.3)	65 (52.4)
Serious AE	49 (38.9)	48 (38.7)
AE leading to permanent treatment discontinuation	25 (19.8)	11 (8.9)
AE leading to death (fatal outcome)*	7 (5.6)	14 (11.3)

No new safety signals were observed[1]

* Musculoskeletal pain or discomfort included back pain, flank pain, musculoskeletal discomfort and pain, neck pain, or pain in extremities.
† Renal disorder included, acute kidney injury, renal failure and impairment, hydronephrosis, or pyelocaliectasis.
‡ Spinal cord or nerve-root disorder included sciatica, radiculopathy, or spinal cord compression.
§ Psychiatric disorder included anxiety, depression, confusion, disorientation, or sleep disorder.
** Adverse events leading to death were assessed during the period from randomization to 30 days after the last treatment administration.

G-CSF was mandated every cycle per trial protocol.[1] Per FDA prescribing information, primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features.[3]

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

Dose and Dose Modification

The FDA-recommended dose of JEVTANA (cabazitaxel) is 20 mg/m^2 administered every three weeks as a one-hour intravenous infusion in combination with oral prednisone 10 mg administered daily throughout JEVTANA treatment. A dose of 25 mg/m^2 can be used in select patients at the discretion of the treating healthcare provider.[3]

Dose Modifications for JEVTANA[1]

Toxicity	Dose modification
Prolonged grade ≥3 neutropenia (>1 week) despite appropriate medication including granulocyte-colony stimulating factor (G-CSF)	Delay treatment until neutrophil count is >1,500 cells/mm^3, then reduce dosage of JEVTANA by one dose level. Use G-CSF for secondary prophylaxis.
Febrile neutropenia or neutropenic infection	Delay treatment until improvement or resolution, and until neutrophil count is >1,500 cells/mm^3, then reduce dosage of JEVTANA by one dose level. Use G-CSF for secondary prophylaxis.
Grade ≥3 diarrhea or persisting diarrhea despite appropriate medication, fluid and electrolyte replacement	Delay treatment until improvement or resolution, then reduce dosage of JEVTANA by one dose level.
Grade 2 peripheral neuropathy	Delay treatment until improvement or resolution, then reduce dosage of JEVTANA by one dose level.
Grade ≥3 peripheral neuropathy	Discontinue JEVTANA.
Hepatic impairment	Administer JEVTANA at a dose of 20 mg/m^2 for patients with mild hepatic impairment and 15 mg/m^2 for patients with moderate hepatic impairment.

Premedication

Premedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity

- **antihistamine** (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine),
- **corticosteroid** (dexamethasone 8 mg or equivalent steroid),
- **H2 antagonist** (ranitidine 50 mg or equivalent H2 antagonist).

Antiemetic prophylaxis is recommended and can be given orally or intravenously as needed.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS cont'd

Hypersensitivity Reactions: Severe hypersensitivity reactions can occur. Premedicate all patients with antihistamines, corticosteroids and H2 antagonists prior to JEVTANA. Observe patients closely, especially during the first and second infusions. Discontinue JEVTANA immediately if severe hypersensitivity occurs and treat as indicated.

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IMPORTANT SAFETY INFORMATION cont'd

WARNINGS AND PRECAUTIONS cont'd

Gastrointestinal (GI) Adverse Reactions: Nausea, vomiting, and severe diarrhea may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trials and mortality related to diarrhea has been reported. Intensive measures may be required for severe diarrhea and electrolyte imbalance. Rehydrate and treat with antiemetics and antidiarrheals as needed. If experiencing grade ≥3 diarrhea, dosage should be modified.

GI hemorrhage and perforation, ileus, enterocolitis, neutropenic enterocolitis, including fatal outcome, have been reported. Risk may be increased with neutropenia, age, steroid use, concomitant use of NSAIDs, antiplatelet therapy or anticoagulants, and prior history of pelvic radiotherapy, adhesions, ulceration and GI bleeding. Abdominal pain and tenderness, fever, persistent constipation, diarrhea, with or without neutropenia, may be early manifestations of serious GI toxicity and should be evaluated and treated promptly. JEVTANA (cabazitaxel) treatment delay or discontinuation may be necessary.

Renal Failure: Cases, including those with fatal outcomes, have been reported. Identify cause and manage aggressively.

Urinary Disorders including Cystitis: Cystitis, radiation cystitis, and hematuria, including that requiring hospitalization, has been reported with JEVTANA in patients who previously received pelvic radiation. Cystitis from radiation recall may occur late in treatment with JEVTANA. Monitor patients who previously received pelvic radiation for signs and symptoms of cystitis while on JEVTANA. Interrupt or discontinue JEVTANA in patients experiencing severe hemorrhagic cystitis. Medical and/or surgical supportive treatment may be required to treat severe hemorrhagic cystitis.

Respiratory Disorders: Interstitial pneumonia/pneumonitis, interstitial lung disease and acute respiratory distress syndrome have been reported and may be associated with fatal outcome. Patients with underlying lung disease may be at higher risk for these events. Acute respiratory distress syndrome may occur in the setting of infection. Interrupt JEVTANA if new or worsening pulmonary symptoms develop. Closely monitor, promptly investigate, and appropriately treat patients receiving JEVTANA. Consider discontinuation. The benefit of resuming JEVTANA treatment must be carefully evaluated.

Use in Patients with Hepatic Impairment: JEVTANA dose should be reduced for patients with mild (total bilirubin >1 to ≤1.5 x ULN or AST >1.5 x ULN) and moderate (total bilirubin >1.5 to ≤3.0 x ULN and any AST) hepatic impairment, based on tolerability data in these patients. Administer JEVTANA 20 mg/m² for mild hepatic impairment. Administer JEVTANA 15 mg/m² for moderate hepatic impairment. Monitor closely.

Embryo-Fetal Toxicity: JEVTANA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of JEVTANA.

ADVERSE REACTIONS (ARs)

The most common all grades adverse reactions and laboratory abnormalities (≥10%) with JEVTANA 20 mg/m² or 25 mg/m² are neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia.

DRUG INTERACTIONS

Avoid coadministration of JEVTANA with strong CYP3A inhibitors. If patients require coadministration of a strong CYP3A inhibitor, consider a 25% JEVTANA dose reduction.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** The safety and efficacy of JEVTANA have not been established in females. There are no human data on the use of JEVTANA in pregnant women to inform the drug-associated risk.
- **Lactation:** The safety and efficacy of JEVTANA have not been established in females. There is no information available on the presence of JEVTANA in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.
- **Females and Males of Reproductive Potential:** Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the final dose of JEVTANA.

Please see accompanying full Prescribing Information, including Boxed WARNING.

References: 1. De Wit R, Kramer G, Eymard JC, et al. CARD: Randomized, open-label study of cabazitaxel (CBZ) vs abiraterone (ABI) or enzalutamide (ENZ) in metastatic castration-resistant-prostate cancer (mCRPC). *N Engl J Med.* 2019. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 11, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **3.** JEVTANA Prescribing Information. Bridgewater NJ: sanofi-aventis U.S. LLC. **4.** Bahl A, Oudard S, Tombal B, et al; for the TROPIC. **5.** Eisenberger M, Hardy-Bessard AC, Kim CS, et al. Phase III study comparing a reduced dose of cabazitaxel (20 mg/m²) and the currently approved dose (25 mg/m²) in postdocetaxel patients with metastatic castration resistant prostate cancer–PROSELICA. *J Clin Oncol.* 2017;35(28):3198-3206. Investigators. Impact of cabazitaxel on 2-year survival and palliation of tumour-related pain in men with metastatic castration-resistant prostate cancer treated in the TROPIC trial. *Ann Oncol.* 2013;24(9):2402-2408. **6.** Supplement to: de Wit R, et al; for the CARD Investigators. *N Engl J Med.* doi: 10.1056/NEJMoa1911206.

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