

# Cabazitaxel

MADE IN GERMANY

Concentrate for Solution for Infusion



Cabazitaxel EVER Pharma is provided as a single vial, ready to dilute formulation and is available in vial sizes covering the common range of patient specific doses for economy and convenience

Cabazitaxel is a third-generation antineoplastic taxane and was the first therapy to show a survival benefit for the treatment of patients with docetaxel-refractory mCRPC.

- **Available as a single vial formulation** – does not require pre-dilution, step saving time and costs
- **Available in 3 presentations** – as the original 60 mg vial and 2 further fill sizes targeted at common patient dose
- **All vial presentations come in CytoWrap®** – for safer handling and transportation



[www.everpharma.com](http://www.everpharma.com)

**EVER**  
PHARMA

# AVAILABLE IN THREE PRESENTATIONS

Designed to match patient needs, with two presentations covering the most common doses.



**45 mg**  
**4.5 ml**



**50 mg**  
**5 ml**



**60 mg**  
**6 ml**

## most common patient doses

BSA m <sup>2</sup>	1.4	1.5	1.6	1.7	1.8	1.9	2.0
Std Dose mg/m <sup>2</sup>	25	25	25	25	25	25	25
Patient Dose mg	35	38	40	43	45	48	50

## mg wastage

<b>45mg/4.5 ml vial</b>	10.0	7.5	5.0	2.5	0.0		
<b>50 mg/5 ml vial</b>						2.5	0.0
<b>60 mg/6 ml vial</b>	25.0	22.5	20.0	17.5	15.0	12.5	10.0

# SINGLE VIAL SYSTEM

- **Dose range specific vial fills mean less wastage** by reducing the amount of left-over product after the patient dose is extracted
- **All presentations are multidose vials with 28 days stability after first opening when stored below 25 °C** versus Jevtana® with only 24 hours at 2-8 °C after diluting concentrate

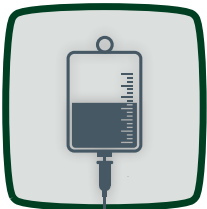


**Less preparation time, wastage and costs**



**Faster preparation than the innovator 2 vial system:**  
it takes more than 5 minutes to dilute Jevtana® concentrate and leave standing before a patient specific dose can be prepared.

Practical Information for medical or healthcare professionals on preparation, administration and handling of JEV TANA 60mg concentrate and solvent for solution for infusion – Sanofi SmPC



**No pre-dilution with solvent required prior to preparing patient specific doses.**

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## Concentrate for Solution for Infusion

<b>Indications</b>	Cabazitaxel EVER Pharma in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen
<b>Active Ingredient</b>	Cabazitaxel
<b>Excipients</b>	Polysorbate 80, Ethanol (anhydrous), Macrogol, Citric acid
<b>Presentations</b>	<ul style="list-style-type: none"><li>■ 45 mg/4.5 ml concentrate for solution for infusion</li><li>■ 50 mg/5 ml concentrate for solution for infusion</li><li>■ 60 mg/6 ml concentrate for solution for infusion</li></ul> (all registered as multidose vials)
<b>Strength</b>	One ml of the concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 10 mg cabazitaxel.
<b>Stability</b>	<ul style="list-style-type: none"><li>■ <b>Unopened:</b> 36 months, does not require any special storage conditions</li><li>■ <b>After 1st Opening:</b> Multi-dose vial: Chemical, physical and microbiological stability of the solution after first opening has been demonstrated for 28 days at not more than 25 °C</li><li>■ <b>After dilution:</b> Chemical and physical stability of the infusion solution has been demonstrated for 48 hours at not more than 25 °C and for 14 days at refrigerated conditions</li></ul>
<b>Primary Packaging</b>	Clear, glass vial closed with a grey bromobutyl rubber stopper sealed with an aluminium cap covered with a plastic flip-off cap
<b>Pack sizes</b>	1 vial per pack. Vials may or may not be sheathed in a protective sleeve.



Plastic sleeving for safer handling

### Cabazitaxel EVER Pharma 10 mg/ml concentrate for solution for infusion

Composition: One ml of the concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 10 mg cabazitaxel. List of excipients: Polysorbate 80, Ethanol anhydrous, Macrogol, Citric acid. Therapeutic indications: In combination with prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen. Contraindications: Hypersensitivity to cabazitaxel, to other taxanes, polysorbate 80 or any excipients. Neutrophil counts less than 1,500/mm<sup>3</sup>. Severe hepatic impairment (total bilirubin >3 x ULN). Concomitant vaccination with yellow fever vaccine. Side effects: very common: Neutropenia, Anaemia, Leukopenia, Thrombocytopenia, Anorexia, Dysgeusia, Dyspnoea, Cough, Diarrhoea, Nausea, Vomiting, Constipation, Abdominal pain, Alopecia, Back pain, Arthralgia, Haematuria, Fatigue, Asthenia, Pyrexia. common: Septic shock, Sepsis, Cellulitis, Urinary tract infection, Influenza, Cystitis, Upper respiratory tract infection, Herpes zoster, Candidiasis, Febrile neutropenia, Hypersensitivity, Dehydration, Hyperglycaemia, Hypokalaemia, Anxiety, Confusional state, Neuropathy peripheral, Peripheral sensory neuropathy, Dizziness, Headache, Paraesthesia, Lethargy, Hypoaesthesia, Sciatica, Conjunctivitis, Lacrimation increased, Tinnitus, Vertigo, Atrial fibrillation, Tachycardia, Hypotension, Deep vein thrombosis, Hypertension, Orthostatic hypotension, Hot flush, Flushing, Oropharyngeal pain, Pneumonia, Dyspepsia, Abdominal pain upper, Haemorrhoids, Gastroesophageal reflux disease, Rectal haemorrhage, Dry mouth, Abdominal distension, Dry skin, Erythema, Pain in extremity, Muscle spasms, Myalgia, Musculoskeletal chest pain, Flank pain, Acute renal failure, Renal failure, Dysuria, Renal colic, Pollakiuria, Hydronephrosis, Urinary retention, Urinary incontinence, Ureteric obstruction, Pelvic pain, Peripheral oedema, Mucosal inflammation, Pain, Chest pain, Oedema, Chills, Malaise, Weight decreased, Aspartate aminotransferase increased, Transaminases increased. uncommon: Cystitis due to radiation recall phenomenon, including haemorrhagic cystitis. unknown: Interstitial pneumonia/pneumonitis and interstitial lung disease. More information available in the summary of product characteristics. Only available on prescription. Last update: July 2020. Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria.