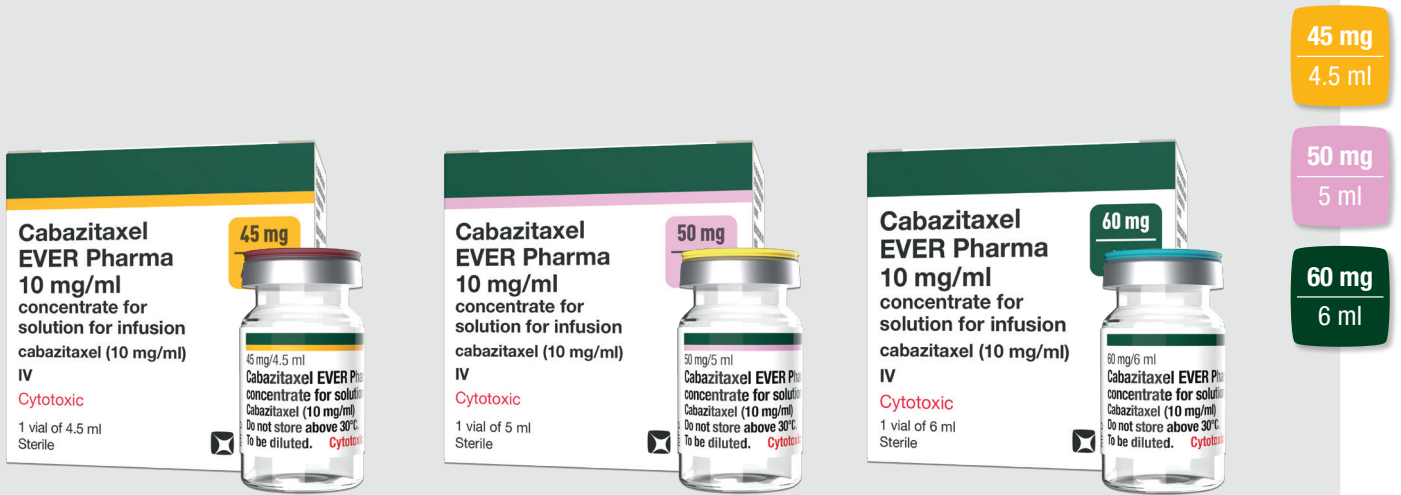


# Cabazitaxel

MADE IN GERMANY

Concentrate for Solution for Infusion



Cabazitaxel EVER Pharma is available in three presentations (45 mg, 50 mg and 60 mg) as a single-vial, ready-to-dilute formulation, supplied in CytoWrap® for safer handling and transportation.

A third-generation antineoplastic taxane, indicated in combination with prednisone or prednisolone for metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing regimen.

- **Single-vial formulation** – no pre-dilution with solvent required, saving preparation time and costs
- **Available in three presentations** – the original 60 mg vial plus two fill sizes targeted at the most common patient doses, reducing wastage
- **Supplied 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 |
|----------------------------------|-----|-----|-----|-----|-----|-----|-----|
| <b>Std Dose mg/m<sup>2</sup></b> | 25  | 25  | 25  | 25  | 25  | 25  | 25  |
| <b>Patient Dose mg</b>           | 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



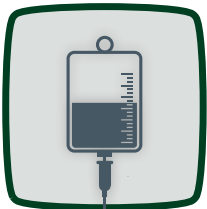
**Less preparation time, wastage and costs**



**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.**

# Cabazitaxel

MADE IN GERMANY

## Concentrate for Solution for Infusion

|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Indications</b>       | 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>          | Each 1 ml of concentrate 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> Multidose vial: chemical, physical and microbiological stability 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 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 be sheathed in a protective sleeve.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Density</b>           | 1.039 g/cm <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |



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.