

# Cabazitaxel

Ready to dilute

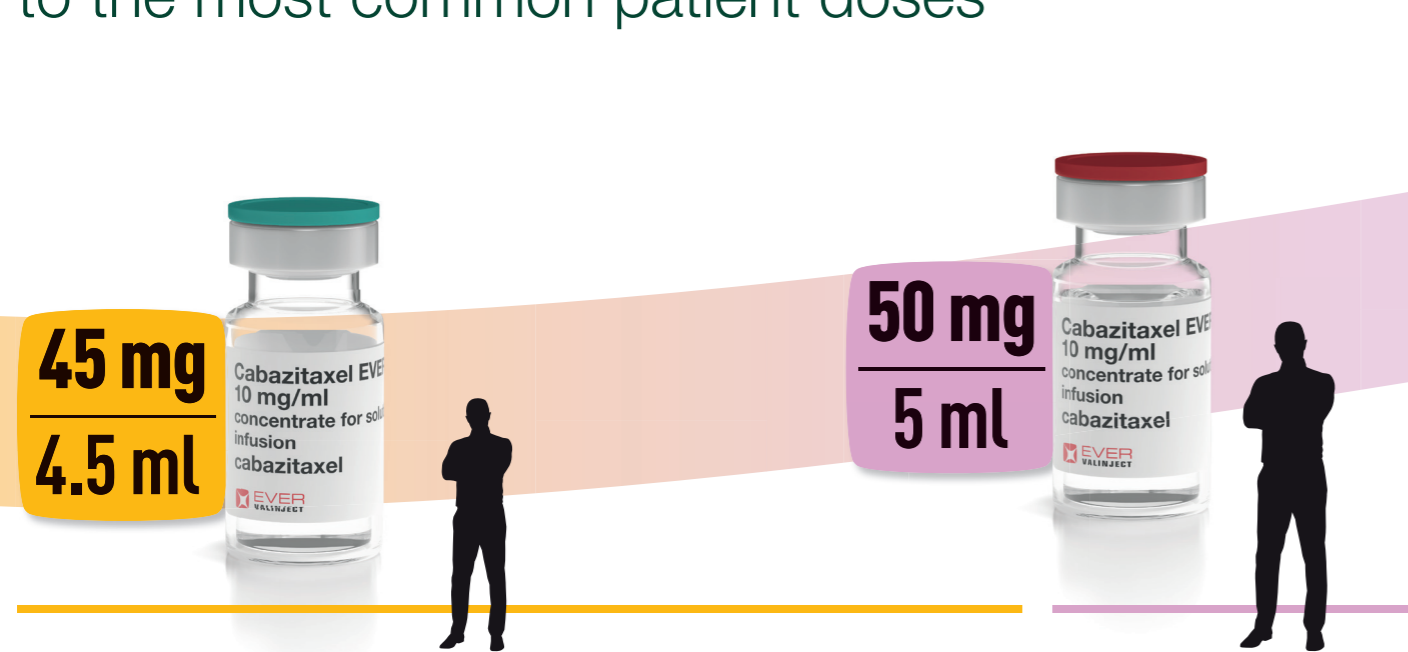


**Cabazitaxel EVER Pharma is provided as a single vial, ready to dilute formulation and is available in vial sizes covering the common range of patient specific doses for economy and convenience**

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 doses
- **All vial presentations come in CytoWrap®** – for safer handling and transportation

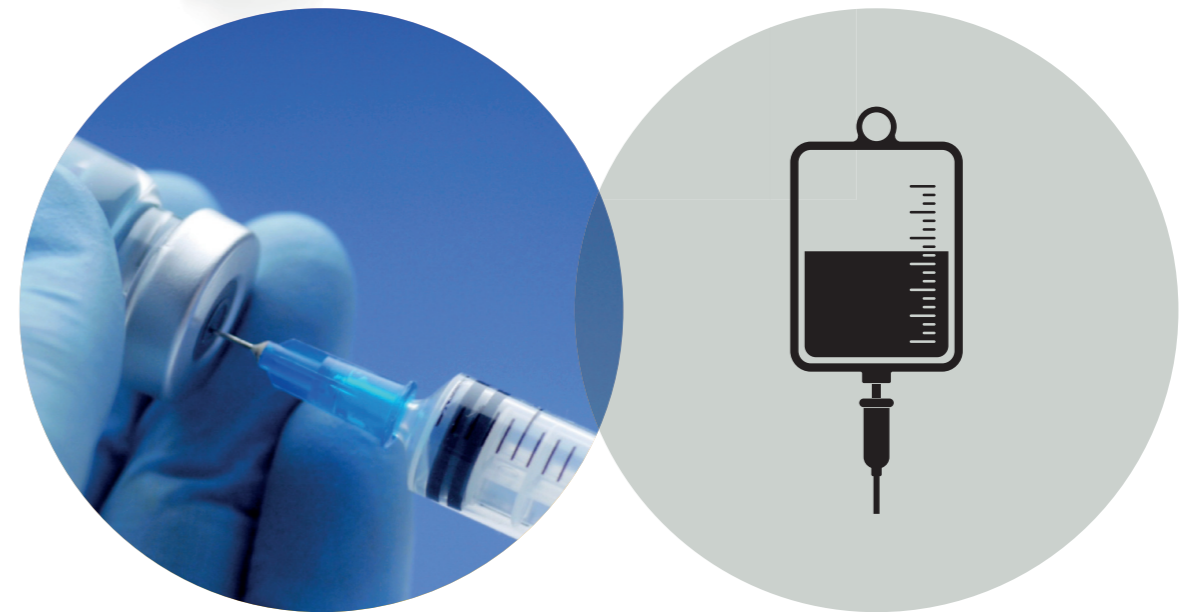
**Cabazitaxel EVER Pharma is available in three presentations** with 2 of these aligned to the most common patient doses



**Single vial system** – no pre-dilution with solvent required prior to preparing patient specific doses



- **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



|                            | 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   | 25 |
| Patient Dose mg            | 35                        | 38   | 40   | 43   | 45   | 48   | 50   |    |
|                            | mg wastage                |      |      |      |      |      |      |    |
| 45 mg/4.5 ml vial          | 10.0                      | 7.5  | 5.0  | 2.5  | 0.0  |      |      |    |
| 50 mg/5 ml vial            |                           |      |      |      |      | 2.5  | 0.0  |    |
| 60 mg/6 ml vial            | 25.0                      | 22.5 | 20.0 | 17.5 | 15.0 | 12.5 | 10.0 |    |

**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<sup>1</sup>

<sup>1</sup> Practical Information for medical or healthcare professionals on preparation, administration and handling of JEVTANA 60 mg concentrate and solvent for solution for infusion – Sanofi SmPC

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## Indications

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

## Active Ingredient

Concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous

## Excipients

Polysorbate 80, Ethanol (anhydrous), Macrogol, Citric acid

## Primary Packaging

Clear, glass vial closed with a grey bromobutyl rubber stopper sealed with an aluminium cap covered with a plastic flip-off cap

## Strength

10 mg/ml concentrate for solution for infusion

## Presentations

45 mg/4.5 ml, 50 mg/5 ml, 60 mg/6 ml (all registered as multidose vials)

## Stability

Unopened

24 months, does not require any special storage conditions

After 1st opening

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

After dilution

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

## Pack sizes

Pack sizes: 1 x 4,5 ml (45 mg), 1 x 5 ml (50 mg), 1 x 6 ml (60 mg)  
Vials may or may not be sheathed in a protective sleeve

### 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.