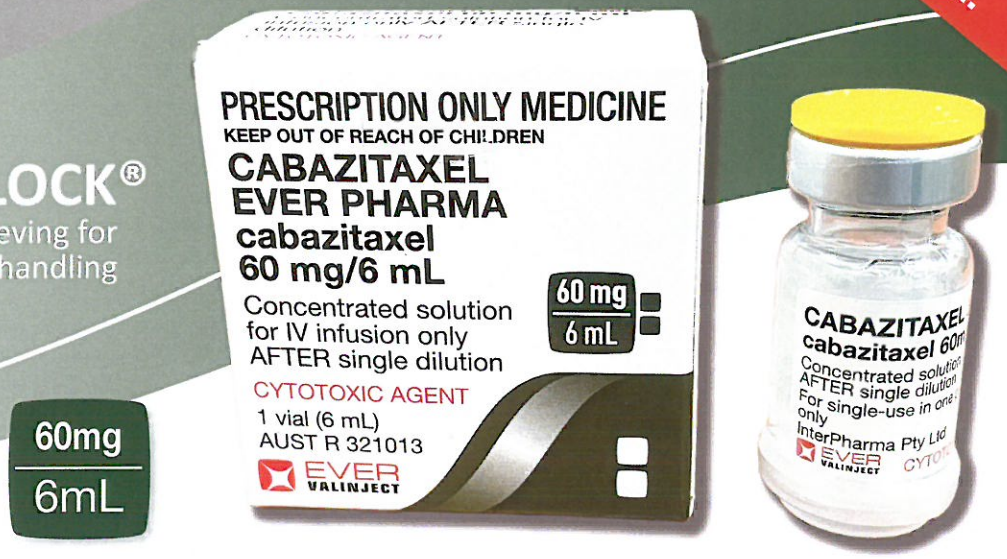
CABAZITAXEL EVER PHARMA

Cabazitaxel 60mg/6mL

NOW AVAILABLE
The First 'Single Vial' Cabazitaxel Ready-To-Use Solution in Australia.

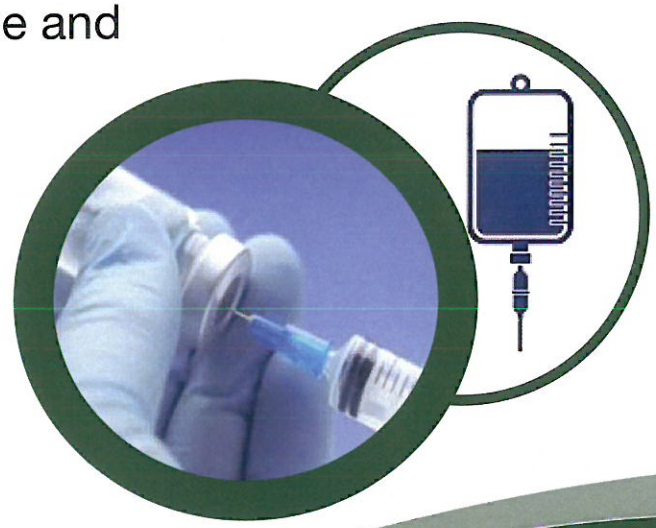
ONCODLOCK®
Plastic sleeving for safer handling



60mg
6mL

- CABAZITAXEL EVER PHARMA is supplied Ready-To-Use to then dilute to the required patient dose

- Single vial system – no pre-dilution with solvent required, saving time and reducing complexity during cytotoxic compounding



- Vial presented in ONCODLOCK® for safer handling and transportation

EVER VALINJECT

Distributed in Australia by: **InterPharma Pty Ltd**
Suite 103, 39 East Esplanade, Manly NSW 2095 · Phone 02 9976 6876
www.interpharma.com.au

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Cabazitaxel 60mg/6mL

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	10mg/ml concentrate for solution for infusion
Presentations	60mg/6ml Vials are sheathed in a protective sleeve ONCODLOCK®
Stability (Unopened)	2 years at room temperature (storage: Do not store above 30°C, do not refrigerate undiluted concentrate)
After 1st opening	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	After final dilution in the infusion bag/bottle, the infusion solution may be stored up to 8 hours below 30°C (including the 1 hour infusion) or for not more than 24 hours at 2°C - 8°C. Extended stability data available on request.

MIMINUM PRODUCT INFORMATION.

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING. FULL PRODUCT INFORMATION IS AVAILABLE FROM: *https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-01700-1&d=20160502161146224483*

CABAZITAXEL EVER PHARMA (CABAZITAXEL) CONCENTRATE FOR INJECTION. Available as 60 mg cabazitaxel in 6 mL concentrated solution for injection in a glass vial with a yellow flip off cap. Contains 1185 mg ethanol 100% (The 45 mg/4.5 mL and 50 mg/5 mL products are not marketed at this time). The concentrate is a clear slightly yellow oily solution. **THERAPEUTIC INDICATIONS:** CABAZITAXEL EVER PHARMA in combination with prednisone or prednisolone is indicated for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel containing regimen. **DOSE AND METHOD OF ADMINISTRATION:** The use of CABAZITAXEL EVER PHARMA should be confined to units specialised in the administration of cytotoxics and it should only be administered under the supervision of a physician experienced in the use of anticancer chemotherapy. Facilities and equipment for the treatment of serious hypersensitivity reactions like hypotension and bronchospasm must be available (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE in FULL PI). **Do not use** PVC infusion containers (bags or bottles) for the preparation of the infusion solution. **Do not use** polyurethane infusion sets (tubing, filter, pumps) for the administration of the infusion solution. Refer to **FULL PI** for further information. **CONTRAINDICATIONS:** History of severe hypersensitivity reactions to cabazitaxel, any of the excipients of cabazitaxel or other drugs formulated with polysorbate 80; Neutrophil counts ≤1,500/mm3; Severe hepatic impairment (total bilirubin > 3 x ULN); Pregnancy and breast-feeding; Concomitant vaccination with yellow fever vaccine (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE and section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS in **FULL PI**). **SPECIAL WARNINGS AND PRECAUTIONS FOR USE: refer to FULL PI. Use in the Elderly:** Elderly patients (≥65 years of age) may be more likely to experience certain adverse reactions including neutropenia or febrile neutropenia with cabazitaxel (see section 4.8 ADVERSE EFFECTS in **FULL PI) Paediatric Use:** The safety and the efficacy of cabazitaxel in children have not been established. **INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS: refer to FULL PI. FERTILITY, PREGNANCY AND LACTATION (refer to Full PI). Use in Pregnancy Category D:**-Cabazitaxel is not recommended during pregnancy. Due to potential exposure via seminal liquid, men with partners of childbearing potential should use reliable contraception throughout treatment and are recommended to continue this for up to 6 months after the last dose of cabazitaxel. There are no adequate and well-controlled studies in pregnant women using cabazitaxel. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the foetus. Women of childbearing potential should be advised to avoid becoming pregnant during treatment with cabazitaxel. Use in Lactation :Cabazitaxel should not be used during breast-feeding. **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:** No studies on the effects on the ability to drive and use machines have been performed. However, based on the safety profile, cabazitaxel may have moderate influence on the ability to drive and use machines as it may cause fatigue and dizziness. Patients should be advised to not drive or use machines if they experience these adverse reactions during treatment. **ADVERSE EFFECTS (UNDESIRABLE EFFECTS): refer to FULL PI. SPECIAL PRECAUTIONS FOR STORAGE:** Store below 30°C. Do not freeze. Do not refrigerate undiluted cabazitaxel concentrate.

NAME AND ADDRESS OF THE SPONSOR:
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