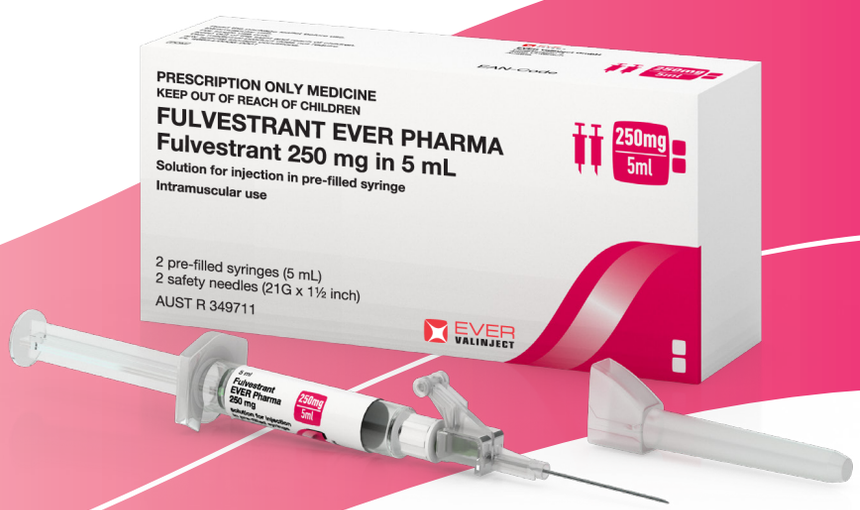
FULVESTRANT EVER PHARMA

Fulvestrant 250 mg in 5 mL

Room Temperature



250mg
5ml

The **first** Fulvestrant in Australia approved for storage at **room temperature**

- **No special requirement for storage at 2°C-8°C**
  - save on refrigerated storage space
  - no management of costly temperature excursions
- **Complete with high quality BD SafetyGlide™ Shielding Hypodermic Needle**
- **European manufacturer with an excellent supply record**

EVER VALINJECT

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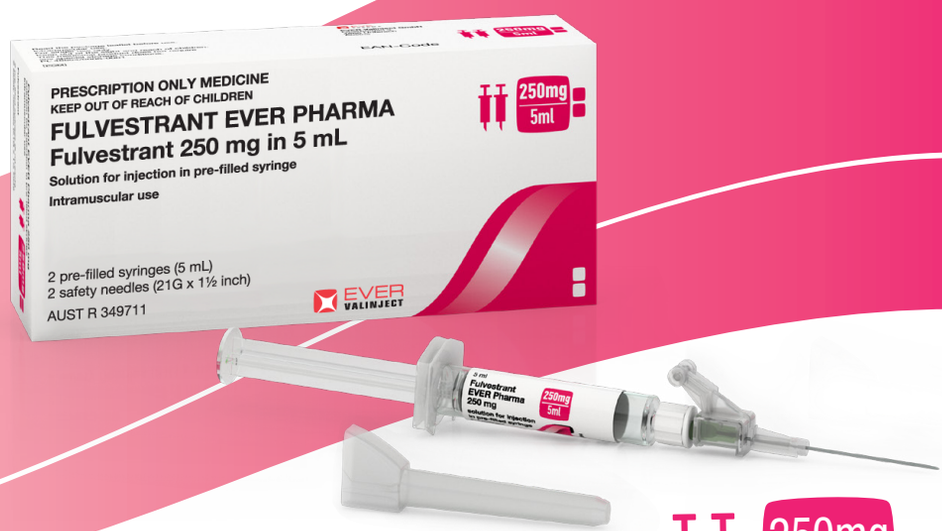

250mg 5ml

The **first** Fulvestrant in Australia approved for storage at **room temperature**

Active Ingredient	Fulvestrant
Excipients	Ethanol (96%), Benzyl alcohol, Benzyl benzoate, Castor oil (virgin)
Presentation	Double Pack: Two clear type I glass pre-filled syringes with bromobutyl rubber stopper (FluorTec coating), polystyrene plunger rod and backstop, fitted with a tamper-evident closure (bromobutyl rubber tip cap), each containing 5 ml solution for injection in pre-filled syringe. 21G x 1½ inch safety needles (BD SafetyGlideTM) for connection to each barrel are also provided.
Strength	One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution. Each ml of the solution contains 50 mg fulvestrant.
Shelf Life	24 months, does not require any special temperature storage conditions

Minimum 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=20160502161146224 83 FULVESTRANT EVER PHARMA 250 mg/5 mL solution for injection is a pre-filled syringe with clear, colourless to yellow, viscous liquid. **INDICATION:** FULVESTRANT EVER PHARMA is indicated for the treatment of postmenopausal women with • hormone-receptor (HR) positive, human epidermal growth factor receptor 2(HER2) negative, locally advanced or metastatic breast cancer who have not been previously treated with endocrine therapy. • HR positive, locally advanced or metastatic breast cancer who have progressive disease following prior endocrine (anti-oestrogen or aromatase inhibitor) therapy. **CONTRAINDICATIONS:** -FULVESTRANT EVER PHARMA is contraindicated in patients with a known hypersensitivity to the drug substance or to any of the excipients; and in pregnancy. **DOSE AND METHOD OF ADMINISTRATION:**- In the absence of incompatibility studies, FULVESTRANT EVER PHARMA must not be mixed with other drugs. Product is for single use in one patient only. Discard any residue. ***Adult females (including the elderly)*** The recommended dose (500 mg) is to be administered intramuscularly as two 5 mL injections, one in each buttock (gluteal area), at intervals of 1 month. An additional 500 mg dose is to be given 2 weeks after the initial dose. It is recommended that the injection be administered slowly (1-2 minutes/injection). Caution should be taken if injecting FULVESTRANT EVER PHARMA at the dorsogluteal site due to the proximity of the underlying sciatic nerve. Patients with hepatic insufficiency - No dose adjustments are recommended for patients with mild hepatic impairment. Caution should be used with FULVESTRANT EVER PHARMA in patients with moderate to severe hepatic impairment, as clearance may be reduced. **Refer to Full PI.** Patients with renal insufficiency - No dose adjustments are recommended for patients with a creatinine clearance greater than 30 mL/min- Refer to Full PI **ADVERSE EFFECTS – refer to full PI. NATURE AND CONTENTS OF CONTAINER:** -FULVESTRANT EVER PHARMA 250 mg/5 mL solution in pre-filled syringes (one (1) or two (2) syringes per pack). Each pre-filled syringe consists of: One 5 mL clear neutral glass (Type 1) barrel containing a nominal 5 mL of FULVESTRANT EVER PHARMA solution for injection and fitted with a tamper evident closure. The syringes are presented in a tray with polystyrene plunger rod and a safety needle (SafetyGlide™) for connection to the barrel. Prescription only medicine (Schedule 4) **SPONSOR:** -InterPharma Pty Ltd, Suite 103, 39 East Esplanade, MANLY NSW 2095. Date of First Approval 1 Oct 2021. FULVESTRANT EVERPHARMA MPI V1.0 – based on PI V1.5 (Oct 2021). InterPharma Pty Ltd

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