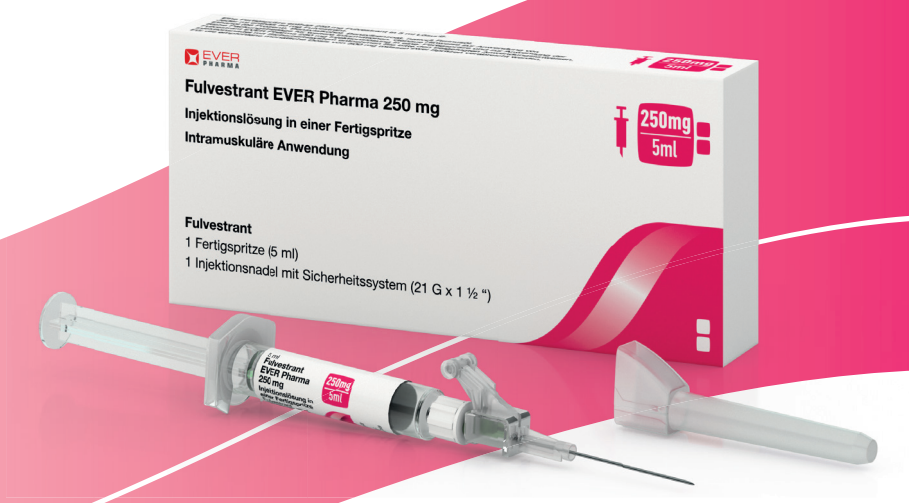
# Fulvestrant

## Room Temperature




250mg 5ml

250mg 5ml

## The **first** Fulvestrant in Europe approved for storage at **room temperature**

Fulvestrant EVER Pharma is indicated as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

- not previously treated with endocrine therapy
- or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy

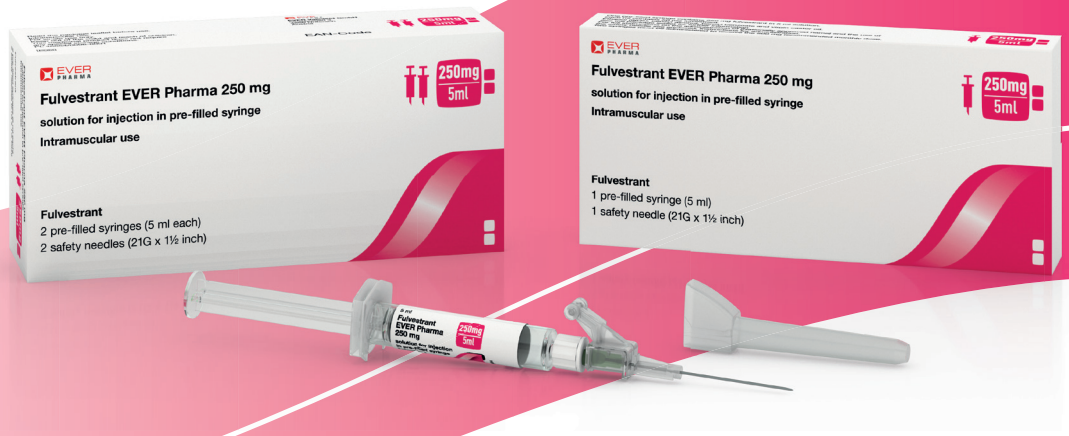
In combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy

- **No special requirement for storage at 2°C-8°C** - save on refrigerated storage space
- **No cold chain transportation** - save on transport costs
- **Complete with high quality BD SafetyGlide™ Shielding Hypodermic Needle**
- **Available as either a single or double pack**

EVER PHARMA

# Fulvestrant

## Room Temperature

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## The **first** Fulvestrant in Europe approved for storage at **room temperature**

**Active Ingredient** Fulvestrant

**Excipients** Ethanol (96%), Benzyl alcohol, Benzyl benzoate, Castor oil (virgin)

**Presentations** 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 [Nationally approved name] solution for injection in pre-filled syringe. 21G x 1½ inch safety needles (BD SafetyGlideTM) for connection to each barrel are also provided.
Also available as a single pack.

**Strength** One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution.
Each ml of the solution contains 50 mg fulvestrant.

**Indications** Fulvestrant EVER Pharma is indicated as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

- not previously treated with endocrine therapy,
- or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy

in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy

**Shelf Life** 24 months, does not require any special temperature storage conditions

FULV/INT/9/2018/1

Fulvestrant EVER Pharma 250 mg solution for injection in pre-filled syringe
Composition: One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution. Each ml of the solution contains 50 mg fulvestrant. This medicinal product contains 10 vol % ethanol (alcohol), i.e. up to 500 mg ethanol per syringe, 500 mg benzyl alcohol in each syringe which is equivalent to 100 mg/ml and 750 mg benzyl benzoate in each syringe which is equivalent to 150 mg/ml. List of excipients: ethanol (96%), benzyl alcohol, benzyl benzoate, castor oil, virgin. Therapeutic indications: 1. as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women: not previously treated with endocrine therapy, or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy. 2. in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy. In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist. For intramuscular use. Contraindications: hypersensitivity to the active substance or to any of the excipients, pregnancy and lactation , severe hepatic impairment . Side effects: very common: hypersensitivity reactions, hot flushes, nausea, elevated hepatic enzymes (ALT, AST, ALP), rash, joint and musculoskeletal pain, asthenia, injection site reactions, common: urinary tract infections, reduced platelet count, anorexia, headache, venous thromboembolism, vomiting, diarrhea, elevated bilirubin, back pain, vaginal haemorrhage, neuropathy peripheral, sciatica, uncommon: anaphylactic reactions, hepatic failure, hepatitis, elevated gamma-GT, vaginal moniliasis, leukorrhea, injection site haemorrhage, injection site haematoma, neuralgiac. More information about pharmaceutical form, posology and method of administration, special warnings and precautions for use, interaction with other medicinal products and other forms of interaction, fertility, pregnancy and lactation, effects on ability to drive and use machines, undesirable effects, overdose, pharmacodynamics properties, pharmacokinetic properties, preclinical safety data, incompatibilities, shelf life, special precautions for storage, nature and contents of the container and special precautions for disposal is available in the summary of product characteristics.
Only available on prescription. Last update: August 2018. Pharmacotherapeutic group: Endocrine therapy, Anti-estrogens, Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, A-4866 Unterach

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