Fulvestrant

Solution for Injection

MADE IN GERMANY

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.

- **Room-temperature stable** – no refrigerated storage or cold-chain transport required, reducing logistical complexity and lowering storage and transport costs
- **Supplied with BD SafetyGlide™ Shielding Hypodermic Needle**

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Indications	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.
Active Ingredient	Fulvestrant
Excipients	Ethanol (96%), Benzyl alcohol, Benzyl benzoate, Castor oil
Presentation	**250 mg/5 ml** solution for injection
Strength	Each 1 ml of solution contains 50 mg fulvestrant.
Stability	**Unopened:** 24 months. No special storage conditions required.
Primary Packaging	Type I glass pre-filled syringe with a bromobutyl rubber stopper, polystyrene plunger rod and backstop, with a tamper-evident closure; supplied with 21G × 1½-inch safety needles.
Pack sizes	1, 2, 4, or 6 pre-filled syringes per pack.

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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