

For the use of a registered oncologist only

# Fulvestrant Injection 250 mg

**FASLODEX<sup>®</sup>**

## Abbreviated Prescribing Information

### QUALITATIVE AND QUANTITATIVE COMPOSITION

One pre-filled syringe contains 250 mg fulvestrant USP in 5 mL solution.

### THERAPEUTIC INDICATIONS

FASLODEX is indicated:

1. For the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant antioestrogen therapy or disease progression on therapy with an antioestrogen.
2. For the treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy
3. 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

### POSODOLOGY AND METHOD OF ADMINISTRATION

**Adult females (including the elderly):** The recommended dose is 500 mg at intervals of one month, with an additional 500 mg dose given two weeks after the initial dose.

FASLODEX should be administered as two consecutive 5 mL injections by slow intramuscular injection (1-2 minutes/injection), one in each buttock. Please refer to full prescribing information to learn about instructions for administration.

When FASLODEX is used in combination with palbociclib, please also refer to the local prescribing information of palbociclib.

#### Special populations

- **Renal impairment:** No dose adjustments are recommended for patients with mild to moderate renal impairment (creatinine clearance  $\geq 30$  ml/min).
- **Hepatic impairment:** No dose adjustments are recommended for patients with mild to moderate hepatic impairment.

### CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients listed in prescribing information
- Pregnancy and lactation
- Severe hepatic impairment (Please refer to full prescribing information)

### WARNINGS & PRECAUTIONS

- FASLODEX should be used with caution in patients with mild to moderate hepatic impairment.
- FASLODEX should be used with caution in patients with severe renal impairment (creatinine clearance less than 30 mL/min).
- Due to the intramuscular route of administration, FASLODEX should be used with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking

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anticoagulant treatment. Caution should be taken while administering FASLODEX at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve.

- There are no long-term data on the effect of FASLODEX on bone.
- FASLODEX is not recommended for use in children and adolescents as safety and efficacy have not been established in this group of patients
- The efficacy and safety of FASLODEX (either as monotherapy or in combination with palbociclib) have not been studied in patients with critical visceral disease.

### FERTILITY, PREGNANCY AND LACTATION

- **Women of childbearing potential:** Patients of child-bearing potential should be advised to use effective contraception while on FASLODEX.
- **Pregnancy:** FASLODEX is contraindicated in pregnancy.
- **Breastfeeding:** Breast-feeding must be discontinued during treatment with FASLODEX.
- **Fertility:** The effects of FASLODEX on fertility in humans has not been studied.

### INTERACTIONS

Dose adjustment is not necessary in patients who are receiving fulvestrant and CYP3A4 inhibitors or inducers concomitantly.

### UNDESIRABLE EFFECTS

The most frequently reported adverse reactions with FASLODEX monotherapy are injection site reactions, asthenia, nausea, rash, joint pains, hypersensitivity reactions, hot flushes and increased hepatic enzymes (ALT, AST, ALP). Please refer to full prescribing information or detailed assessment of adverse events.

### PHARMACOLOGICAL PROPERTIES

#### Mechanism of action

Fulvestrant is a competitive oestrogen receptor (ER) antagonist with an affinity comparable to oestradiol. Fulvestrant blocks the trophic actions of oestrogens without any partial agonist (estrogen-like) activity. The mechanism of action is associated with down-regulation of estrogen receptor protein levels.

#### Pharmacokinetic properties

After administration of FASLODEX long-acting intramuscular injection, fulvestrant is slowly absorbed and maximum plasma concentrations ( $C_{max}$ ) are reached after about 5 days. Administration of FASLODEX 500 mg regimen achieves exposure levels at, or close to, steady state within the first month of dosing. Fulvestrant is highly (99%) bound to plasma proteins. CYP3A4 is the only P450 isoenzyme involved in the oxidation of fulvestrant; however, non-P450 routes appear to be more predominant in vivo. The major route of excretion is via the faeces, with less than 1% being excreted in the urine. The terminal half-life ( $t_{1/2}$ ) after intramuscular administration is governed by the absorption rate and was estimated to be 50 days.

### PHARMACEUTICAL PARTICULARS

#### Excipients

- Ethanol (96%); Benzyl alcohol; Benzyl benzoate; Castor oil

#### Shelf life

Refer Outer Carton of the pack

#### Storage

Store and transport in a refrigerator (2°C - 8°C).

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**Presentation**

The pre-filled syringe presentation consists of:

Two clear type 1 glass pre-filled syringes with polystyrene plunger rods, fitted with a tamper-evident closure, containing 5 mL FASLODEX solution for injection. A safety needles (BD SafetyGlide™) for connection to the barrel are also provided.

**FASLODEX is a registered trademark of AstraZeneca group of companies.**

For more information, refer full prescribing Version 6, dated 16/03/2018

**For Further information, please contact:**



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