PRESCRIBING INFORMATION

FASLODEX® 250mg solution for injection (fulvestrant)

Consult Summary of Product Characteristics before prescribing.

**Indication:** Faslodex is indicated as monotherapy for the treatment of oestrogen 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 antioestrogen therapy, or disease progression on antioestrogen therapy. Faslodex is also indicated 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 luteinising hormone releasing hormone (LHRH) agonist.

**Presentation:** One pre-filled syringe contains 250mg fulvestrant in 5ml solution. Each pack contains two pre-filled syringes. Safety needles (BD SafetyGlide) are also provided.

**Dosage and Administration:** Adult females (including the elderly): 500mg at monthly intervals, with an additional 500mg dose given two weeks after initial dose. When Faslodex is used in combination with palbociclib, consult palbociclib SmPC. Prior to the start of combination treatment, and throughout its duration, pre/perimenopausal women should be treated with LHRH agonists according to local clinical practice. Administered intramuscularly as two consecutive injections, one in each buttock (gluteal area). Exercise caution if injecting at the dorsogluteal site due to the proximity of the sciatic nerve. **Paediatric population:** Faslodex is not recommended for use in children or adolescents. The safety and efficacy have not been established in this age group. **Renal impairment:** No dose adjustments are needed for patients with mild to moderate renal impairment (creatinine clearance ≥ 30 ml/min). Safety and efficacy have not been evaluated in patients with severe renal impairment. **Hepatic impairment:** No dose adjustments are recommended for patients with mild to moderate hepatic impairment, use with caution as fulvestrant exposure may be increased. No data available in patients with severe hepatic impairment.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients, pregnancy or breast-feeding patients and in patients with severe hepatic impairment.

**Warnings and Precautions:** Use with caution in patients with mild to moderate hepatic impairment or severe renal impairment. Use with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment. Thromboembolic events are commonly observed in women with advanced breast cancer in clinical studies and should be taken into consideration when prescribing Faslodex to patients at risk. Injection site related events including sciatica, neuralgia, neuropathic pain and peripheral neuropathy have been reported. There are no long-term data on the effect of fulvestrant on bone. There is a potential risk of osteoporosis with Faslodex. Efficacy and safety of Faslodex (either as monotherapy or in combination with palbociclib) have not been studied in patients with critical visceral disease. When Faslodex is combined with palbociclib, also consult palbociclib SmPC. Fulvestrant may interfere with antibody based-estradiol assays and may result in falsely increased levels of estradiol. **Excipients:** Contains 10% w/v Ethanol i.e. up to 500 mg per injection, equivalent to 10 ml of beer or 4 ml of wine (which may be harmful for patients suffering from alcoholism and high-risk groups e.g., patients with liver disease and epilepsy) and Benzyl alcohol (which may cause allergic reactions).
**Drug Interactions:** Dosage adjustment is not necessary for patients co-prescribed Faslodex and CYP3A4 inhibitors or inducers.

**Pregnancy and Lactation:** Patients of childbearing potential should use effective contraception during treatment with Faslodex and for 2 years after the last dose. Patients must be informed of the potential hazard to the foetus and potential risk for loss of pregnancy if they become pregnant whilst taking Faslodex. Breast-feeding must be stopped during treatment.

**Ability to Drive and Use Machines:** Asthenia (a loss of strength) has been reported during treatment with Faslodex, therefore caution should be observed if experiencing this symptom when driving or operating machinery.

**Undesirable Events: Faslodex as monotherapy:** Consult Faslodex SmPC for a full list of side effects. **Very common:** Hypersensitivity reactions, hot flushes, nausea, asthenia, injection site reactions, elevated hepatic enzymes (ALT, AST, ALP), rash, joint and musculoskeletal pain. **Common:** Reduced platelet count, vomiting, diarrhoea, anorexia, urinary tract infections, venous thromboembolism, headache, back pain, elevated bilirubin, vaginal haemorrhage, neuropathy peripheral, sciatica. **Uncommon:** Hepatic failure, hepatitis, elevated gamma-GT, vaginal moniliasis, leukorrhoea, injection site haemorrhage, injection site haematoma, neuralgia and anaphylactic reactions. **Faslodex combined with palbociclib:** Consult Faslodex SmPC and palbociclib SmPC. **All severity grades - Very common:** Infections, neutropenia, leukopenia, anaemia, thrombocytopenia, decreased appetite, nausea, stomatitis, diarrhoea, vomiting, alopecia, rash, fatigue, AST increased and pyrexia. **Common:** Dysgeusia, lacrimation increased, vision blurred, dry eye, epistaxis, dry skin, asthenia and ALT increased. **Uncommon:** Febrile neutropenia. For further details of adverse reactions, particularly neutropenia, please consult Faslodex SmPC.

**Legal category:** POM.

**Marketing Authorisation Number:** EU/1/03/269/002

**Presentation & Basic NHS Cost:** 2 x 5 ml pre-filled syringes: £522.41

**Marketing Authorisation Holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden.

**Further Information is Available From:** AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

FASLODEX® is a trade mark of the AstraZeneca group of companies. SAFETYGLIDE is a trade mark of Becton Dickinson and Company

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Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to AstraZeneca by visiting [https://aereporting.astrazeneca.com](https://aereporting.astrazeneca.com) or by calling 0800 783 0033.